



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

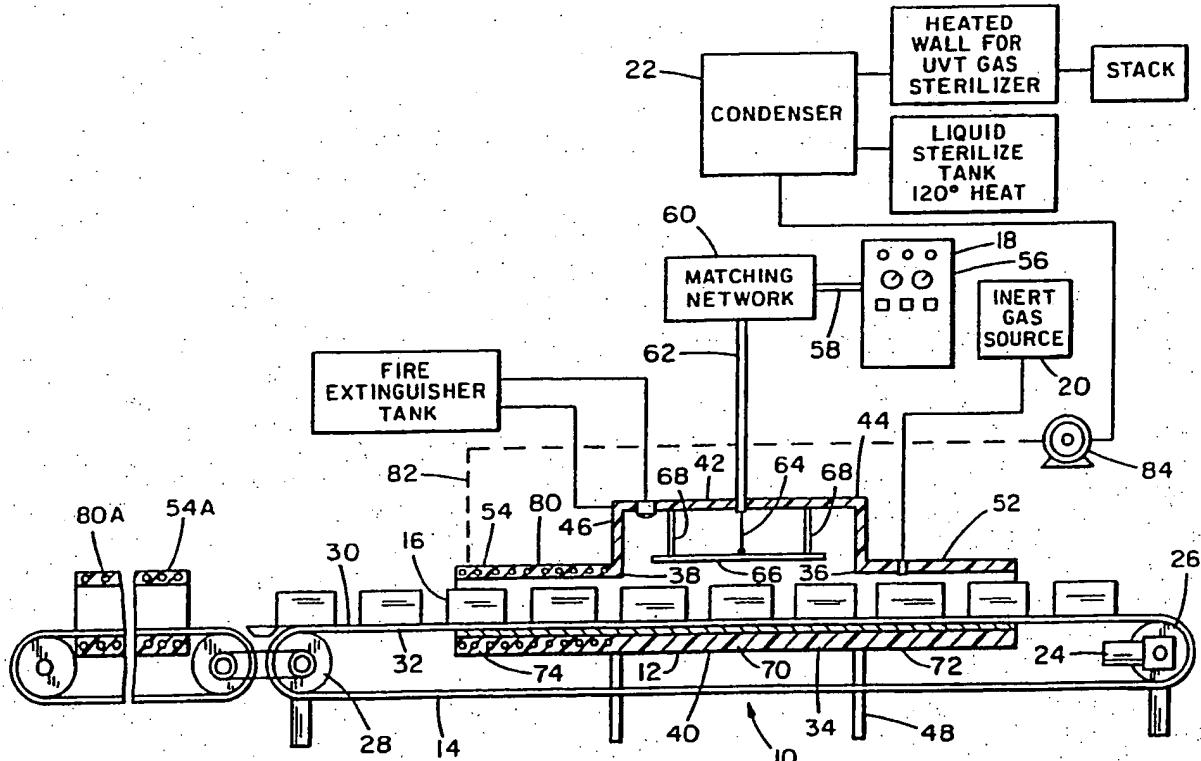
(51) International Patent Classification 5 :	A1	(11) International Publication Number: WO 91/15247
A61L 2/04, 2/12		(43) International Publication Date: 17 October 1991 (17.10.91)

(21) International Application Number: PCT/US91/02196	(74) Agents: WATT, Phillip, H. et al.; Fitch, Even, Tabin & Flannery, Room 900, 135 South LaSalle Street, Chicago, IL 60603 (US).
(22) International Filing Date: 28 March 1991 (28.03.91)	
(30) Priority data: 502,293 30 March 1990 (30.03.90) US	(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent).
(71) Applicant: IIT RESEARCH INSTITUTE [US/US]; 10 West 35th Street, Chicago, IL 60616-3799 (US).	
(72) Inventors: BRIDGES, Jack, Edgar ; 1937 Fenton Lane, Park Ridge, IL 60068 (US). SRESTY, Guggilam, Challaiah ; 8241 South Mason, Burbank, IL 60459 (US). HELD, Jeffrey, S. ; 900 North Lake Shore Drive, Chicago, IL 60611 (US). SHARP, James, W. ; 621 South Bristol Lane, Arlington Heights, IL 60005 (US). BAJZEK, Thomas, J. ; 164 North Walnut, Wood Dale, IL 60191 (US).	

Published

With international search report.

(54) Title: METHOD AND APPARATUS FOR RENDERING MEDICAL MATERIALS SAFE



(57) Abstract

Infectious medical materials (16) is rendered innocuous by heating heterogeneous medical materials (16) having wet and dry portions with a radio frequency electrical field (34). The medical materials (16) are exposed to the radio frequency field (34) in order to heat the medical waste. The medical waste (16) may include sorted medical or veterinary waste which after heat treatment may be shredded and recycled.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America

METHOD AND APPARATUS FOR RENDERING

MEDICAL MATERIALS SAFE

BACKGROUND OF THE INVENTION

5

The present invention relates generally to a method of sterilizing medical materials and more particularly to a method and apparatus for sterilizing medical materials by exposing the materials to radio frequency waves. The term medical materials encompasses medical waste, veterinary waste, and medical products. The problems with current medical waste handling methods, like the problems of solid waste disposal in general, are becoming increasingly acute. Solid waste is primarily disposed of by burning or by burial in landfill. Both of the methods have severe disadvantages. Burning of solid waste liberates waste particles and fumes which contribute to acid rain and other pollution of the atmosphere. Burying the waste results in possible leaks of toxic chemicals into the surrounding earth and contamination of ground water supplies. Although increasing amounts of solid waste are being recycled, which alleviates the problems of incineration and burial, presently available recycling methods do not provide a complete solution to the disposal problem.

Waste disposal is of even more urgent concern when the waste comprises possibly infectious medical waste. Such infectious medical waste is a by-product of veterinary and medical care. For example, regulated medical waste consists of: (1) cultures and stocks of infectious agents and associated biological materials; (2) pathological wastes; (3) human blood and blood products; (4) contaminated sharps, including needles, syringes, blades, scalpels, and broken glass; (5) animal waste; (6) isolation waste, including gloves and other disposable products used in the care of patients with serious infections; and (7) unused sharps. These wastes

can generally be divided between (a) general medical waste, including cultures and stocks of infectious agents, associated biologicals, pathological waste, and human blood and blood products; (b) veterinary waste, 5 including animal waste; and (c) waste that is predominately plastic, such as the contaminated and unused sharps and isolation waste. The predominately plastic waste also includes metal as well. Hospitals typically segregate waste by types. Contaminated sharps 10 and isolation waste, however, are of special concern as they may carry highly dangerous pathogens such as AIDS virus or hepatitis virus. Sharps in particular have caused widespread public concern when observed washed up on beaches or in public areas.

15 Hospitals and other generators of medical and veterinary waste employ three methods of waste handling: (a) on-site incineration of the waste, (b) on-site steam autoclaving of the waste followed by later shipment to a landfill for burying, and (c) collection of the waste by 20 a licensed waste hauler with no on-site processing.

Many hospital incinerators, even those located predominately in urban areas, emit pollutants at a relatively high rate. The Environmental Protection Agency has identified harmful substances in the emissions 25 of such hospital incinerators. They include metals such as arsenic, cadmium and lead, organic compounds, such as ethylene, dioxins and furans, acid gases and carbon monoxide as well as soot, viruses and pathogens. Emissions from these incinerators may be a more 30 significant public health hazard than improper dumping [Steven K. Hall, "Infectious Waste Management: A Multifaceted Problem," *Pollution Engineering*, 74-78 (Aug. 1989)].

Although steam autoclaving may be used to 35 sterilize waste before further processing, it is expensive and time consuming. Heat denatures the

proteins and microorganisms causing protein inactivation and cell death in a short time. Temperature monitoring devices such as thermocouples, and biological indicators, such as heat resistant Bacillus stearothermophilus spores, may be used to assure effective sterilization.

U.S. Patent No. 2,731,208 to Dodd teaches a steam sterilizing apparatus for disposing of contaminated waste which incorporates shredding the waste ("including paper containers such as used sputum cups," col. 1, lines 28-29). Dodd teaches blowing steam into a container full of waste and processing only limited types of items. The Dodd system has the disadvantage of depositing the shredded final mixture into a sewer, which would cause further environmental problems.

Whether or not the hospital first autoclaves its medical wastes, including broken needles and glass, the waste is then turned over to a licensed waste hauler for transport to a landfill or other depository. U.S. Patent No. 3,958,936 to Knight discloses compaction of hospital waste for more efficient landfill disposal. Specifically, the reference teaches the application of heat in the range of about 204°C. to 316°C. to hospital and other waste to melt the plastic and convert it into a hard compact block for safer disposal in landfills. The waste is disinfected by the high temperatures, and sharps, such as needles, become embedded in the plastic where they are a reduced mechanical hazard. However, this method suffers from the disadvantage of requiring relatively high temperatures necessitating large energy expenditures and landfill disposal. Metropolitan landfills are becoming filled, and unauthorized dumping is a problem.

A further area of concern is the sterilization of medical products prior to use. By medical product is meant any product which must be sterilized prior to use in health care. This is exemplified but not limited to

needles, syringes, sutures, bandages, scalpels, gloves, drapes, and other disposal items. Many reusable items also must be provided in sterile form. Widespread current sterilization methods include the use of 5 autoclaving, ethylene oxide, and ionizing radiation such as gamma radiation. The heat and humidity of autoclaving are quite damaging to many disposable metal products. Ethylene oxide and ionizing radiation are preferred commercially in those cases.

10 In order to sterilize medical products, poisonous ethylene oxide gas may be used in a closed chamber containing the products to be sterilized. For effective sterilization, not only must the ethylene oxide concentration be controlled carefully, but the 15 temperature, humidity, and porosity of the sterilizer load also must be carefully regulated. Ethylene oxide is relatively slow to dissipate from plastics and its use may require that medical products be stored until the ethylene oxide concentration decreases to a safe level.

20 Ethylene oxide also must be carefully vented to the atmosphere subsequent to the sterilization cycle in order to avoid poisoning operators of the sterilization apparatus.

25 Ionizing radiation, such as gamma radiation, may be used to sterilize medical products within their packaging; however, it must be administered at such high doses that many plastics become yellow and brittle due to the gamma rays having altered the structure of the polymers of which they are made. For example, U.S. 30 Patent No. 3,940,325 to Hirao teaches methods for adjusting the formulas of plastics for medical syringes to avoid yellowing and cracking due to exposure to sterilizing gamma radiation. Other substances may also be damaged by exposure to gamma radiation. Such ionizing 35 radiation sterilizes because its high energy photons damage and thereby inactivate the DNA of organisms such

as bacteria and viruses. As a result of the inactivation of the DNA, cells lose their ability to reproduce and thereby cause infections. On a large scale industrial basis, ionizing radiation, especially gamma radiation from cobalt 60, has been used to sterilize medical products prior to their use in patients. However, the radiation levels necessary to sterilize may also damage the product being sterilized.

Other methods have been suggested for sterilization of medical products. For instance, U.S. Patent No. 3,617,178 to Clouston teaches a method of improving sterilization efficiency by increasing hydrostatic pressure. Elevated hydrostatic pressure causes sterilization resistant bacterial spores to germinate, or begin to grow. However, it has no effect on viruses. Bacterial germination, which converts the bacteria from their environmentally resistant spore form, makes the bacteria more sensitive to radiation, so that lower doses may be employed. Clouston further teaches optimizing the hydrostatic pressure effect by adjusting the temperature up to 80°C. According to Clouston, elevated pressure in heated fluid or moist gas is essential to the method. Elevated temperature alone has a negligible effect. Furthermore, the pressure, heat, or moisture treatment taught by Clouston is intended to cause bacterial spores to germinate thereby rendering them more vulnerable to sterilization techniques, not to sterilize or inactivate microorganisms.

In contrast, U.S. Patent Nos. 4,620,908 to Van Duzer and 3,704,089 to Stehlik teach prefreezing injectable proteins and surgical adhesive prior to irradiation with gamma radiation from cobalt 60 for aseptic manufacture of those materials. U.S. Patent No. 3,602,712 to Mann discloses an apparatus for gamma irradiation and sterilization of sewage and industrial waste.

Besides gamma radiation, other types of electromagnetic radiation have been considered as potential sterilants in known systems. Microwaves are increasingly being investigated for rapid sterilization of individual medical devices as well as shredded medical waste. Recently, an experiment showed that metallic instruments could be sterilized in only 30 seconds in a microwave oven (New York Times, "Science Watch Microwave Sterilizer is Developed," June 20, 1989). That particular method, however, suffers from the drawback that only a few such metallic instruments can be treated at a particular time. It is not particularly applicable for treatment of medical waste in bulk, and in particular for treatment of medical waste which has been bagged.

United Kingdom Patent No. 1 406 789 to Boucher discloses a microwave system for the surface sterilization of reusable laboratory, medical, and dental instruments in a moist atmosphere at a lower temperature than those presently used and in a shorter time. The system is intended to render aseptic reusable instruments for medical use and generates electromagnetic energy having frequencies between 100 megahertz and 23000 megahertz. Boucher emphasizes that "his invention deals exclusively with surface sterilization" and that he "does not intend to cover such special cases" as "'in-depth' sterilization" (page 1, lines 58-67). Boucher teaches that only through a combination of proper humidification with the thermal and nonthermal effects of microwave radiation can reproducible and satisfactory results be obtained with a wide variety of species, including thermoresistant spores" (page 1, lines 77-83). Boucher teaches the placement of the object to be sterilized in a gas-tight container with a source of water vapor.

Soviet Union Patent No. 1,123,705 also discloses a method of sterilizing medical instruments for reuse by UHF treatment. For injection needles it

discloses a final temperature of 160°C. to 470°C. and for acupuncture needles it discloses a final temperature of 160°C. to 270°C.

Systems are also known for treatment of 5 disposable medical waste utilizing microwaves. This system first shreds the waste, sprays the shredded waste with water, and passes the wet shredded waste through a microwave chamber designed to raise the temperature of the wet shredded waste to 205°C. to sterilize it. After 10 the sterilization step, the system compresses the sterilized shredded waste and packages it for shipment to landfills or incinerators (The Wall Street Journal, p. B33, Apr. 10, 1989). One potential problem with this 15 system is that shredding before sterilization could release infectious particles to the environment and may thus spread contagion. Another problem is the ultimate disposal of the waste; it persists in landfills or may pollute the air when incinerated.

U.S. Patent No. 3,547,577 to Loverch discloses 20 a machine for treating garbage by shredding, compressing the shredded garbage into briquettes, and sterilizing the briquettes with gas. After shredding the garbage is separated into magnetic and nonmagnetic portions. The 25 sterilization step employs ethylene gas which requires temperature control. The briquettes are maintained at a temperature of about 54°C.

Further, microwaves are limited in their 30 penetration and are ineffective for heating when applied to large scale, boxed medical waste of the type which comprises the waste disposal problem today. Microwaves do not heat very effectively because they do not penetrate very deeply. Most of the heat is generated near the surface and quickly dissipates into the 35 surroundings, in part because it is not well conducted into the center portions of the boxed medical waste. In contrast, radio frequency waves at relatively low

- 8 -

frequency can penetrate boxed medical waste more deeply.

Like microwaves, radio frequency waves are a form of electromagnetic energy. They also transfer energy directly into materials, primarily by the

5 interaction of their time-varying electric fields with molecules. Radio frequency waves may be applied by connecting a radio frequency alternating current to a pair of electrodes. Between the two electrodes an alternating radio frequency electromagnetic field having

10 a time-varying electric field component is established. When objects are placed between the electrodes in the time-varying electric field, the time-varying electric field partially or completely penetrates the object and heats it.

15 Heat is produced when the time-varying electric field accelerates ions and electrons which collide with molecules. Heat also is produced because the time-varying electric field causes molecules, and particularly those with a relatively high electric dipole

20 moment, to rotate back and forth as a result of the torque placed upon them by the time-varying electric field. Most large molecules, or molecules with evenly distributed charge, have relatively low or nonexistent dipole moments and are not very much affected by the

25 radio frequency time-varying electric field. Small molecules, in particular with polar groups, have relatively large electric dipole moments and thus have relatively large torques exerted upon them by the time-varying electric field. In particular, highly polar

30 molecules, like water, experience relatively large torques and as a result are rotated by the time-varying electric field, thereby transferring mechanical energy to their surroundings as internal energy or heat. Lower frequency time-varying electric fields penetrate deeply

35 and heat objects more evenly. Relatively high frequency time-varying electric fields do not penetrate as deeply,

but heat more rapidly the portions of objects they interact with.

It should be noted that a time-varying electric field is always accompanied by a time-varying magnetic field, except where destructive cancellation occurs with interference patterns. For most materials being considered here, the principal heating mechanism arises from the electric fields. These fields can cause both ohmic heating via induced ionic currents and dielectric heating via molecular stressing from the internal electric fields. For very moist materials, the presence of the accompanying time-varying magnetic field can also induce eddy-currents which can also heat the material. Also, some type of combined effect of magnetic fields and heat may occur. While the ensuing discussion is presented in context of an electric field effect, it should be understood that the effects of accompanying time-varying magnetic field are defined here for simplification as part of the electric field phenomena.

Because different materials are composed of different types of molecules with differing electric dipoles, they heat at different rates when exposed to a given time-varying electric field. For example, plastics, which are formed of very large polymer molecules, are not heated by time-varying electric fields as rapidly as water. Metal objects may or may not be easily heated when exposed to time varying electric fields either in the radio frequency or microwave region. The high conductivity of the metal objects tends to short out the electric fields and rescatter them. As a consequence, there are many conditions where metal objects are difficult to heat, as exemplified by the metal liner of the interior microwave ovens. On the other hand, such time-varying fields can also induce substantial currents which flow on the outside of the metal objects. Under certain circumstances heating

- 10 -

effects will occur on the surface of the metal object which, in the case of a small needle, the heat is readily diffused into the interior. In addition, the presence of long, thin metal objects in an electric field causes enhancement of the electric field intensity near the ends of the metal objects and a diminution or shadowing of the fields near the middle. Thus, if the electric field is parallel to the axis of the metal object, strong electric fields will exist near the tips and weak electric fields will exist near the center of the rod or needle. Such field enhancements can lead to arcing and possible fires. In addition, the field suppression or shadowing of such metal objects is also an unwanted feature if the presence of a single electric field vector is relied upon in its entirety to provide the sterilization. The failure of the radio frequency electromagnetic field to penetrate the object causing surface heating only, or the opposite failure of the materials to absorb the electric field energy, causes uneven heating of the medical waste. The uneven heating is exacerbated because the medical waste usually comprises mixed materials which are difficult to heat effectively using radio frequency energy due to the presence of areas of high field absorption, such as are due to metals and concomitant shadowing and cold spots. In addition, similar but less pronounced absorption effects are found with water molecules. Thus, when heterogeneous or mixed medical wastes have wet and dry portions, it may be seen that only the wet portions of such material would be heated. Mixed loads such as hospital wastes were considered impossible to sterilize by radio frequency energy because the waste contains a wide variety of materials, each having different dielectric properties. A great concern was that the presence of a sufficient number of metallic sharps would lead to arcing, causing ignition of the accompanying dry wastes. Another concern was that even

if fire was not started, the differential energy absorption of fluids and sharps would leave dry objects unsterilized.

In fact, other attempts to kill microorganisms with radio frequency energy have been considered unsuccessful. In his 1980 review effects of microwave irradiation on microorganisms, Advances in Applied Microbiology 26:129-45, Chipley cites an experiment of applying radio frequency energy to bacteria and viruses which grow on tobacco. The experiment found no effect of the radio frequency energy on the bacteria and viruses. In another study of radio frequency energy on contaminated liquid food, there was no showing of "selective killing effect" except when ethanol was added.

In the same review, Chipley cited numerous tests of microwaves on microorganisms and concluded that "results of tests for viability of B. subtilis spores also showed identical death curves compared with those obtained by conventional heat." On the other hand, however, Chipley cites several references which support the view that microwave irradiation has collateral thermal and nonthermal effects. [For example, Culkin and Fung (1975) found that microbial destruction occurred at reduced temperatures and shorter time periods when the material was exposed to microwaves as compared to conventional heating methods. Wayland et al., 1977 also demonstrated the interdependence of heat and microwave effects in the studies of spores of B. subtilis.

U.S. Patent No. 2,114,345 to Hayford discloses a radio frequency applicator with electroscopic control for destroying bacteria in bottled beer and similar products. Hayford teaches an apparatus for sterilizing a series of small objects. The radio frequency field must be constantly readjusted by the electroscopic control. There is no teaching or suggestion that large scale sterilization of heterogeneous waste could be carried out.

- 12 -

U.S. Patent No. 3,948,601 to Fraser et al. teaches the indirect use of radio frequency energy in sterilizing medical and hospital equipment as well as human waste. The reference teaches the use of radio frequency energy for heating gases, particularly argon, and exciting them so that they ionize into a plasma having a temperature of approximately 100 to 500°C. The reference teaches that a cool plasma at a temperature of only 25 to 50°C. and very low pressure may effectively sterilize an article. However, sterilization by plasma does not suggest the direct use of radio frequency waves in sterilization since it is the chemical reactive effect of the plasma which presumably performs the sterilization function rather than the direct or thermal effects of radio frequency energy on pathogens contained on the material. It may be appreciated that only those portions of the equipment and waste actually contacted by the plasma would be treated.

Reprocessing of the waste, and especially medical waste, is also vital for several reasons. Even if the medical waste has been rendered innocuous by the destruction of any pathogens associated therewith, there is still the problem of the disposal of the bulk material including the plastics, the sharps, and fibrous material such as gowns, diapers, and the like. The material is relatively bulky and landfills, particularly in many urban areas, have become filled. In addition, older landfills may leak and nonpathogenic but chemically polluting substances may leak into surrounding ground water, causing health hazards. Thus, burying the sterilized medical waste is becoming less attractive. Further, merely burning the sterilized medical waste can pollute the atmosphere and cause acid rain. Current reprocessing technology should be employed to process the sterilized medical waste for effective utilization and proper disposal. What is needed is a method for

sterilizing the medical waste and destroying the pathogens thereon and disposing of the sterilized waste in a manner which is harmless to health care workers, waste handlers, and the public at large.

5 A series of investigations has been undertaken as to sterilization, especially for food. This has resulted in patents or inventions wherein the material to be treated is housed in a microwave transparent container such that the material can be heated at vapor pressures 10 which coexist with temperatures of 120°C. These include Gray U.S. Patent No. 3,494,723; Nakagawa U.S. Patent No. 4,808,782; Stenstron U.S. Patent No. 4,808,783; Landy U.S. Patent No. 3,215,539; Utosomi U.S. Patent No. 3,885,915; and Fritz U.S. Patent No. 4,775,770. All of 15 these patents disclose heating homogeneous material in some form of pouch or pressure container where the material, typically food, is homogeneous. They do not address the special problem considered here where the material is heterogeneous and contains sharps, moist 20 materials and dry materials.

SUMMARY OF THE INVENTION

The present invention provides a method and 25 apparatus for processing medical materials such as medical and veterinary waste and medical products which sterilizes the materials by heating them with radio frequency energy. The invention sterilizes bagged bulk medical waste by heating it with a radio frequency 30 electric field. The medical waste is heterogeneous, that is, it comprises wet and dry materials such as dressings, diapers, tissue and the like and material such as plastic gloves, plastic syringes and the like. The medical waste also contains metal containing sharps as such hypodermic 35 needles, suturing needles, scalpels and the like. The waste is exposed to a radio frequency electric field

having a frequency of in the range of 500 kilohertz to 600 megahertz, preferably about 18 megahertz or 64 megahertz. The lower frequencies of operation are preferred to assure good depth of penetration of the
5 electric fields into the more moist material. If microwave frequencies are used (above 900 MHz), the depth of penetration is often less than a few centimeters. The depth of penetration is decreased by increasing the moisture content.

10 While not wishing to be bound by any particular theory, it is noted that the time-varying electric field heats the water on the wet portions and boils off a portion of it. The evaporated water or water vapor apparently travels by convection and diffusion throughout
15 the bag containing the medical waste and may condense on the cooler, dry portions because, other than the metal-containing sharps, dry material has not been heated substantially by the time-varying electric field. It is believed that the condensation of moisture on the
20 formerly dry material gives up heat of vaporization and thereby transfers heat to the previously dry material. It is believed that this transfer of moisture makes the materials relatively homogeneous with respect to water content. This permits all of the material to be rapidly
25 heated volumetrically by the field. The condensed moisture on or in the previously dry material can now absorb energy from the electric field. This generates heat within or on the previously dry material which is now rapidly heated by the field. In one embodiment of
30 the invention, the bags of medical waste are confined within pressure vessels within the electric field and the medical waste is rapidly heated above 90°C., slightly below the boiling point of water at atmospheric pressure. Nevertheless, this temperature kills the
35 pathogens on the waste.

One step of the pressure-vessel method comprises heating the medical materials with radio frequency energy, possibly within one or more bags housed within a closed container, to raise the internal 5 temperature to about 90°C. In another embodiment, the temperature may be raised to 100°C. The pressure within the bags, if used, increases to a point where the bags will burst thereby coupling within the container vapor transfer from one bag to another. The heating may then 10 continue to 120°C.

The vapor-containing version of this invention is suitable to treat a wide variety of wet and dry 15 conglomerations of permeable material which must be raised to temperatures below or close to that of the vaporization point of water. The use of radio frequency heating in such a container creates volumetric heating and reduces the time requirements associated with 20 autoclaving. The invention also is useful for the treatment of certain nonuniform moisture content commodities which are highly permeable, such as breakfast 25 cereals, tobacco, and whole grains, which are highly permeable to gas flow while at the same time often require heating treatments to sterilize the produce, to kill insect infestations and to equalize the moisture contents.

In another embodiment, to implement the vapor-containing version of the process, the materials to be treated may be collected and eventually placed in a plastic bag capable of withstanding temperatures, for 30 about 15 minutes, of just above the vaporization point of water which, in this case for sea-level atmospheric pressure, would be just above 100°C. When the bags are filled, these are sealed and placed in a fiberboard box container. An additional vapor seal such as a fiber 35 reinforced plastic sheet or cylinder may be applied over a number of boxes which can then be placed on a pallet for ease of transport through the RF heating facility.

- 16 -

Thus, by selecting this type of specific packaging, several of the requirements for the successful vapor-containment, sterilization process are realized. First of all, a vapor impermeable barrier is placed around the material. Secondly, the heat capacity of the vapor barrier is small since the wall thickness of the plastic material is quite thin. Thirdly, thermal transfer outside the treatment material is inhibited by the use of the fiberboard box. Such fiberboard boxes are relatively good thermal insulators, owing to the air-sack-like spacing between the inner and outer portions of the fiberbox material.

One of the embodiments of the invention additionally comprises the step of transferring heated medical waste to a heat-soaking area which maintains the elevated temperature for about 45 minutes. The temperature is maintained in an energy effective and cost efficient fashion in order to provide extra assurance that all pathogens are destroyed by the heat.

One advantage of the above-mentioned pressure vessel which retains vapors up to temperatures of at least 120°C. is obtaining sufficient utilization of the radio frequency energy by not allowing the water vapor to escape. Thus, energy losses which might occur in a nonpressurized container due to the need to vaporize the water are avoided.

In some versions, the walls of the cavity or belt are heated to a temperature that is comparable to the temperature of the material being processed. As a consequence, in the case of the invention at hand, little or no energy is transferred out of the items to be heated. The purpose of minimizing this transfer is that if the surface is too hot, the material becomes sticky and gummy and thereby eventually clogs the mechanics of the system. On the other hand, if the wall material is significantly lower than that of the material being

processed, energy is lost from the material being processed. In the case of wet or moist material where a high energy absorption occurs, this may not be a significant problem, but it can be significant in the case of very dry materials. These have little dielectric absorbing ability and therefore have little capability to simultaneously heat themselves and the adjacent walls. To overcome this, a preferred embodiment of the invention employs the use of peripheral guard heaters along the walls such that the wall temperature assumes approximately the same temperature as that of the material being processed. Alternatively, insulated wall materials may be used which have low thermal conductivity and heat capacity, whereby the heated gases from the material being processed can easily heat the wall so that they can be heated such that the wall temperature can immediately rise to the temperature of the material being processed.

However, it may be advantageous in certain situations not to treat the material or waste in a pressure resistant container, but rather the material can be exposed in an unpressurized container to the radio frequency energy such that the temperature of the material or medical waste is first heated to about 90°C. Further heating to at least 120°C. substantially evaporates all of the water contained in the medical waste. Hence in another embodiment of this invention, to avoid possible underheating effects associated with shadowing through the presence of metallic objects in the waste, the material in the container can be tumbled such that all portions of the material are exposed to all three vector orientations of the electric field.

The tumbling process also ensures exposure of all the material to the electric fields to take advantage of collateral thermal and nonthermal effects which may exist at about 90 and may allow complete sterilization to

- 18 -

be accomplished without a significant degree of vaporization.

Another embodiment of the invention also comprises steps of further processing the medical waste by presorting the material into recyclable plastic or refuse derived fuel, comminuting or shredding both types of materials, repackaging and shipping to commercial users.

Therefore, in view of the foregoing, it is a primary object of the present invention to render innocuous or sterilize medical materials by heating them with radio frequency waves. A further object or aspect of the invention is to dispose of sterilized medical and veterinary waste in an environmentally safe manner.

Additional objects, advantages, and novel features of the invention will be set forth in part in the description which follows, and in part will become apparent to those skilled in the art upon examination of the following, or may be learned by practice of the invention.

20

BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 is a flow diagram of the steps involved in rendering bagged medical waste innocuous by heat treatment with radio frequency electromagnetic fields;
- 25 FIGS. 2A, 2B, 2C and 2D are schematic representations of radio frequency treatment units and radio frequency energy sources which may be used in the radio frequency sterilization of infectious medical waste;
- 30 FIG. 3 is a schematic view of a system for continuously sterilizing bagged and boxed medical waste by using radio frequency energy;
- FIG. 4 is a section of a radio frequency reactor of FIG. 3, showing the electric field vector lines and equipotential lines generated within the radio frequency treatment unit;

FIG. 5 is an isometric view of the radio frequency treatment unit of FIG. 3 and a conveyor associated therewith showing details of the orientation of the conveyor with respect to an exciter plate within the reactor and the radio frequency treatment unit;

FIGS. 6A, 6B and 6C are plan and front side elevational views of a different type of radio frequency treatment unit which can be used without the exciter plate, the top and bottom of the shielded cavity serving as termination points for the electric fields, thereby simplifying the cavity design and permitting operation at higher frequencies.

FIGS. 7A, 7B and 7C are graphs of a normalized frequency power density in a single-end driven radio frequency treatment unit and a radio frequency treatment unit driven at opposite ends by radio frequency energy having two different frequencies to provide uniform average power throughout a major portion of the treating chamber of the unit;

FIG. 8 is a schematic view of a semicontinuous waste sterilization system employing the radio frequency treatment unit illustrated in FIGS. 6A, 6B and 6C;

FIG. 9 is a flow diagram showing the steps of waste sterilization carried out by the apparatus of the present invention;

FIG. 10 is an elevational view, shown partly in section, of a pressure vessel for holding bagged medical waste for placement inside the radio frequency reactor of the apparatus of the present invention;

FIGS. 11A and 11B show side and end elevational views of the pressure vessel of FIG. 10 and the mounting and driving apparatus therefor;

FIG. 12 is a diagrammatic view of the vapor treatment system associated with the apparatus shown in FIGS. 3 and 8; and

- 20 -

FIG. 13 is a diagrammatic representation of an alternative vapor treatment system employing condensation and waste treatment.

5

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The method of the instant invention is illustrated in the flow diagram of FIG. 1 and consists of gathering medical waste from a waste source in a step 2 and placing the waste in a thermally insulated vapor sealed container, which may consist of a plastic bag, in a step 3. In a step 4, the vapor sealed container may be placed inside a box and the box loaded on a pallet. The box and pallet are then sealed in a vapor seal comprising a shrink-fit plastic or the like to prevent the escape of moisture from the container during processing. The vapor sealed containers are placed in a radio frequency field applicator in a step 5 and a radio frequency power source energizes the applicator to heat the material for a sufficient time to evaporate some of the water therein, transfer the resulting water vapor to dry portions of the material where it condenses and thereby wets and heats the entire volume of medical waste in a step 6. After heating of the medical waste is completed and the waste is sterilized by heat inactivation of the microorganisms thereon the sterilized medical waste may be transferred to a landfill in a step 7.

Referring now to the drawings and especially to FIG. 3, an apparatus 10 for continuous waste treatment is generally shown in FIG. 3 and includes a radio frequency treatment unit 12 and a waste transport system or conveyor 14 for feeding bagged and/or boxed heterogeneous medical waste 16 to the radio frequency treatment unit 12. A source of radio frequency energy 18 is connected to the radio frequency treatment unit 12 to energize it and an effluent handling system 22 is connected to the

radio frequency treatment unit 12 to treat gases and vapors evolved during the heating of the bagged and boxed medical waste 16. Also a source 20 of inert sweep gas, such as nitrogen, is connected to the radio frequency treatment unit 12 for driving oxygen therefrom to avoid combustion of the medical waste being heated.

The radio frequency treatment unit 12 includes an applicator or reactor 34 providing a reaction chamber to which radio frequency energy is applied. The design of the applicator 34 to produce the required electric field and exposure time is of interest. Such applicators may be divided into three basic groups: (1) TEM parallel plate applicators where the wavelength of the excitation frequency is large or comparable to the dimensions of the reactor 34; (2) TE or TM controlled mode applicators where the dimensions of the reactor 34 are comparable to or several times the wavelength of the excitation frequency; and multi-mode TE and TM applicators where the maximum dimension of the reactor 34 is typically 4 or more times the wavelength of the excitation frequency. Typically with the multi-mode TE or TM applicators, the modes are not controlled such that a number of peaks and nulls of the electric field exist within the heating unit, such as exists typically in a microwave oven.

FIGS. 2A, 2B, 2C and 2D illustrate the transition from a parallel plate TEM applicator 34 to a controlled limited mode TE or TM applicator. FIG. 2A shows a reactor 34 formed of two parallel plates 66 and 70 with the material 16 placed between the upper and lower plates 66 and 70, respectively. Voltage is applied between the upper and lower plate by means of a tuning coil which is driven from the RF source 18. As long as the wavelength of the applied voltage is large compared to the dimensions of the applicator 34, and the box 16 is well within the extended portions of the metal plates 66, 70, a uniform field can be applied.

- The applicator shown in FIG. 2A is an example of the TEM applicator and is limited to the lower frequencies, and because the dielectric absorption is roughly proportional to the "nth" power of the frequency
- 5 (where n ranges from 0.3 to 1.0 for frequencies below the 300 MHz) and the square of the electric field, substantially higher electric intensities for lower frequencies are required to cause the same heating effect as might be expected for higher frequency operation.
- 10 Higher frequency operation is possible in a controlled mode heating cavity 34 such as shown in FIG. 2D, which is an example of the TE or TM applicator. The transition of the reactor 34 from the embodiment of FIG. 2A to that shown in FIG. 2D is illustrated in FIGS. 2B and 2C. The
- 15 parallel plates 66, 70 shown in FIG. 2A are resonated with the thin wire series inductance 67. However, by reducing the value of this inductance, higher frequency resonances are possible. Nevertheless, there is an upper limit to the frequency at which this resonance can be
- 20 made to occur if just a single thin wire solenoidal inductor is employed. To increase the resonant frequency, straps 69 on the sides of the two parallel plates 66, 70 can be employed as shown in FIGS. 2B and 2C, with power applied by way of a launching coil or turn
- 25 67. Eventually this arrangement is transformed into the controlled TE or TM applicator as shown in FIG. 2D. The controlled TE or TM applicator 34 is defined where $1/2$ wavelength is comparable to the large dimension of the box. This limits the number of permissible modes and
- 30 allows controlled and uniform heating. In the case of a microwave oven, the dimensions are in the order of 6 to 8 half wavelengths. This results in uncontrolled modes and nonuniform heating.
- In another embodiment, the waste transport system 14 also includes a conveyor motor 24 which drives an input conveyor drum 26.

An output idler conveyor drum 28 also comprises a portion of the conveyor 14 and a conveyor belt 30 engages both the input driven drum 26 and the output idler drum 28. A portion 32 of the chain mail conveyor belt 30 extends through the radio frequency treatment unit 12 for carrying the bagged medical waste 16 therethrough for treatment.

The radio frequency treatment unit 12 comprises a radio frequency chamber 34 having a radio frequency chamber inlet opening 36 and a radio frequency chamber outlet opening 38. The radio frequency treatment unit 12 has a length of 18m, a width of 4.5m and a height of 3m. The radio frequency chamber 34 comprises a bottom wall 40, a top wall 42, an inlet wall 44, an outlet wall 46, a first side wall 48, and a second side wall 50. Each of the chamber walls is constructed of highly conducting material such as copper or aluminum. Typically 6 millimeter aluminum can be used, which allows the chamber walls to be self-supporting. Also 3 millimeter thick copper could be used in conjunction with additional physical support. The radio frequency treatment unit 12 also includes an inlet tunnel 52 connected to the inlet wall 44 at the inlet opening 36. The inlet tunnel 52 has a rectangular cross section and is dimensioned to act as a wave guide below cutoff to prevent the radiation of electromagnetic fields from the interior of the radio frequency chamber 34 to the environment while allowing the bagged medical waste 16 to be carried freely into the radio frequency chamber 34 by the conveyor belt 30. Likewise, a wave guide below cutoff forms an output tunnel 54 from the outlet 38 at the outlet wall 46 to carry bagged sterilized medical waste 16 out of the vicinity of the radio frequency treating chamber 34 without allowing radio frequency energy from the radio frequency treating chamber 34 to leak into the surroundings.

- 24 -

In order to energize a radio frequency electromagnetic field and, in particular, the time-varying electric field component thereof, within the radio frequency treating chamber 34, the radio frequency energy generator 18 is provided and includes a radio frequency current generator 56 connected to a coaxial cable 58 for feeding power therethrough. A matching network 60 receives the radio frequency energy from the coaxial cable 58 to which it is connected. A second coaxial cable 62 is also connected to the matching network 60 to carry the radio frequency power therefrom. That coaxial cable has a center lead 64 which penetrates the top wall 42 of the radio frequency chamber 34 and is connected to a vertically movable substantially rectangular conductive exciter plate 66. The outer conductor is connected to the top wall 42 and grounded. The exciter plate 66 is suspended by a plurality of nonconductive ropes 68, preferably nylon or orlon, from the top wall 42 of the radio frequency chamber 34. This allows the exciter electrode 66 to be moved with respect to the bagged medical waste 16 to provide a spatially uniform, time-varying electric field to heat the bagged medical waste 16 relatively uniformly. A three millimeter thick copper bottom plate 70, which is substantially flush with a pair of bottom plates 72 and 74 of the inlet and outlet wave guide below cutoff tunnels 52 and 54, respectively, comprises the bottom plate of what is in essence a biplate configuration reactor. Typically, the bottom plate 70, as well as the walls 42, 44, 46, 48, 40, and 50 of the radio frequency chamber 34, are maintained at ground potential while the exciter plate 66 is excited by the radio frequency energy fed through the coaxial cable 62.

It is particularly important in the practice of the present invention that the exciter plate 66 be movable, as this allows adjustment of the relatively

uniform portion of the electric field within the radio frequency chamber 34. This is important because the size of the containers containing the bagged medical waste 16 may vary from time to time. It is important that when 5 the containers are traveling through the center portion of the radio frequency heating chamber 34, they be subjected to a substantially spatially uniform time-varying electric field so that the contents thereof are uniformly heated.

10 In the case of the parallel plate exciter, the dimensions of the box 16 compared with the dimensions of the electrode 66 are important in order to assure reasonably uniform electric field and resultant heating effects. To determine the relationship between the box 15 dimensions and the size of the electrode exciter, the data in FIG. 4 were developed. This shows equi-potential lines (horizontal) coupled with the displacement current lines (near-vertical) for a limited extent exciter electrode 66 centrally located in a large conducting 20 box. The relative electric field at any location can be developed by determining the dimensions of a square at any location and a similar square in the uniform region (far right) and dividing the maximum dimensions of this 25 uniform field square by a similar dimension of the square at the desired location.

It can be seen therefore, if the guard distance, that is the distance from the edge of the box to the downward projection of the edge of the electrode, 30 is equal to the height of the electrode, that very little field distortion occurs and that the electric field in the region to the right of this point is reasonably uniform. Further studies show that if the edge of the box is moved farther to the left, field distortion occurs such that the electric field is significantly less near 35 the ground plane and therefore the material of the box would experience a significantly lower heating rate.

- 26 -

Guard distances which are equal to about one-fourth or less than the height of the exciter electrode are relatively unsatisfactory.

- On the other hand, it is seen that as the
5 height of the box is increased, the field distortion near
the edge of the electrode is such as to contribute excess
field intensities, particularly where the height of the
box is 75% of that of the exciter electrode and the guard
distance is equal to one-quarter of the electrode height.
10 Data taken from this plot are summarized in Table 1. It
may be seen that guard distances as little as one-fourth
the height of the electrode are acceptable but, on the
other hand, the maximum height of the box probably should
preferably be no more than 67% of the height of the
15 exciter electrode. The reason for this is that as the
box enters from the left going into the right, it
encounters increasingly high levels of electric field
near the edge of the electrode. As a consequence, excess
field intensity can occur there which can lead to
20 potential gradients and arcing phenomena. To ensure
against such effects as well as over or under heating,
the normalized heating rate during entry wear the top
edge of the box should not vary more than 1.5 to 1.0 for
the parallel plate type of heater shown in FIG. 3. Where
25 the bulk of the water is not evaporated but rather
repositioned, heating ratios of 2.0 to 1.0 can be
tolerated. Where the bulk of the water is evaporated and
heating is contained beyond the vaporization point, the
heating rate variation should be less than 1.5 to 1.0.
30

TABLE 1. HEATING POTENTIAL (E^2) NORMALIZED TO THE HEATING POTENTIAL IN THE UNIFORM FIELD REGION AS A FUNCTION OF THE BOX HEIGHT RELATIVE TO THE HEIGHT OF THE ELECTRODE AND FOR RELATIVE GUARD LENGTHS.

Dimensions Relative to Electrode Height, h	Normalized Heating Potential, (E^2)				
	Box Height	Guard Length	Top of Box	Bottom of Box	Top of Box During Entry
10	0.5	0.5	0.92	0.96	1.0
	0.5	0.25	0.92	0.88	1.0
	0.67	0.5	1.25	0.96	1.21
	0.67	0.25	1.10	0.88	1.21
	0.75	0.5	1.44	0.96	1.8
	0.75	0.25	1.2	0.88	1.8

In the present embodiment, in particular for the type of reactor shown in FIG. 3, an 18 megahertz radio frequency current generates an 18 megahertz radio frequency electric field within the radio frequency chamber 34 to heat the medical waste 16 within the hospital waste containers. It may be appreciated that the hospital or medical waste may comprise a wide variety of waste having many different dielectric constants. For instance, the sharps will include metals in which collected displacement currents will be induced by the time-varying electric field. Very moist materials will also be included, as well as quite dry materials such as gloves and the like. In particular, the moist materials couple well with the radio frequency field due to the fact that the dipole moments of the water molecules cause the water molecules to have a torque exerted thereon by the electric field when it is unaligned with the dipole moments. This causes the molecules to be moved, in particular rotated by the field. The water molecules then transfer disordered kinetic energy to the materials upon which they are in contact, causing them to be heated.

When the medical waste 16 is first placed in the radio frequency chamber 34, the wet portions of the medical waste 16 are rapidly heated by the radio frequency energy, causing water vapor to be evolved therefrom. The water vapor is dispersed by convection and diffusion throughout the bags of hospital waste and condenses on the dry waste therein, due to the fact that the dry waste has been relatively unheated until it comes in contact with water. The condensation of the water vapor on the cooler material transfers heat thereto by giving up heat of vaporization. More importantly, however, the condensed vapor wets the formerly dry material whereby the water is volumetrically heated by the time-varying electric field, transferring thermal energy to the previously dry waste and causing the waste within the bag to be substantially uniformly volumetrically heated. Since the frequency of the time-varying electric field is selected to be 18 megahertz, or, in the alternative 64 megahertz, the electric field penetrates well into typical waste bags, and the entire volume of medical waste within the bags is substantially uniformly heated once the water is dispersed, allowing the waste to be rapidly heated. Once a minimum temperature of about 90C is reached, virtually all pathogenic organisms are all destroyed by the heat, and the waste is sterilized.

In one embodiment of the invention, as shown in FIG. 3, the exit tunnel 54 is lined with electric resistance heaters 80, which are means for heat soaking the medical waste, if a further margin of safety is desired. As the bagged medical waste 16 passes through the exit tunnel 54, the electrical resistance heaters 80 transfer sufficient heat energy via radiation to prevent heat loss from the hazardous waste boxes 16. This heat is not sufficient to raise the temperature of boxes 16 further, but it is only sufficient to maintain the

temperature of the boxes at the exit. As a result, the exit tunnel 54 in combination with a similar tunnel 54a of much longer length will provide a means for heat soaking the hazardous medical wastes over the appropriate period of time. This can be done with a relatively low power consumption in order to hold the hazardous medical waste at the desired temperature for up to approximately 45 minutes. In addition, such a heating tunnel in combination with the RF source heating method provides a means to heat the medical waste in a controlled manner such that combustion does not occur and the plastic does not melt or partially pyrolyze. This temperature is sufficient to kill all pathogenic organisms within the medical waste 16. It would, of course, be difficult, if not impossible, to use such electric resistance heaters or other infrared radiative heaters solely to heat bulky materials like the hospital waste from ambient temperature due to the fact that infrared heaters provide essentially surface and not volumetric heating. That is, in accordance with the present invention, the waste is first heated volumetrically to the desired temperature and held at that temperature by surface heating. If the surface is maintained at the desired temperature, the interior cannot cool.

Doors may be provided at the distal ends of the inlet wave guide below cutoff 52 and the outlet wave guide below cutoff 54 as well as the heat soak entrance and exit to trap gases generated by the heating within the unit. These gases might, like the contents of the medical waste containers 16, be combustible. As a result, the inert gas system 20 floods the radio frequency heating chamber 34 as well as the inlet tunnel 52 and the outlet tunnel 54 with nitrogen. The flow is a counter flow in the inlet tunnel 52 keeping oxygen out of the system in order to prevent fires. The nitrogen flush also provides other important features to the invention.

Since the injection point for the nitrogen flush is near the inlet tunnel 52, or actually on it, the relatively cool nitrogen enters the radio frequency treating area at approximately the same temperature as the hazardous waste 16. Nitrogen is carried in the same direction as the hazardous waste 16 and is heated thereby by conduction, radiation and convection from the heated medical waste 16. As a result, an effective temperature ramp is provided from the inlet portion of the radio frequency heating chamber 34 to the outlet portion by the flowing of the gas in combination with the gradual heating. Due to the fact that the gas flows in the direction in which the temperature is increasing, refluxing of any vapors released from the bagged medical waste 16 is prevented to the cooler input hospital waste by the directed flow of the nitrogen gas and thus prevents condensation on the cooler exterior of the containers, which could inhibit volumetric heating. The nitrogen gas also operates as a sweep gas and carries effluents out through an effluent exit port 82 which comprises a portion of the inert gas system 20. The effluent exit port 82 is connected to a blower 84 which is connected to the effluent treatment system 22.

The effluent treatment system 22, as may best be seen in FIG. 12, processes the effluents evolved in the heating of the infectious medical waste. These effluents essentially consist of steam, air and inert gases, such as the nitrogen sweep gas, as well as some hydrocarbons generated during heating of the waste and possibly pathogens that might have been released during the waste processing. Under normal conditions, though, all of the pathogens would be inactivated or destroyed by the radio frequency heating. The effluent exits through the duct from the radio frequency heating chamber 34 and passes a hydrocarbon sensor 92 connected to the duct 82 for determining whether hydrocarbons are present. If

hydrocarbons are present in excess of a predetermined value, an air injection system 94 injects air into the effluent gas stream so that a combustible mixture of air and hydrocarbons, as well as inert gases, is fed to a vapor preheater 96. The vapor preheater is a heat exchanger fed with exhaust gases from downstream equipment. A hydrocarbon sensor 98 is connected to a condenser duct 100 adapted to receive an inlet from the condenser. The gases are then fed through a duct 102 to a catalytic oxidation system 104 which may be purchased from Allied Signal UOP or other commercial suppliers. The catalytic oxidation system receives fuel such as propane or natural gas, if needed, via a fuel delivery line 106. The catalytic oxidizer also includes a catalyst, such as Torvex catalyst available from Englehart, for the oxidation of hydrocarbons into carbon dioxide and water. The oxidizable components are oxidized by contact with the catalytic oxidizer and resulting hot combustion products are fed through a combustion output line 108 to a blower 110 which directs the hot combustion products through a hot gas output line 112 into the heat exchanger 96 to conserve heat energy by transforming heat from the hot combustion products before they are vented to the environment to the effluent gases in the input duct. The combustion products are then vented through the output duct 100 to the environment. The hydrocarbon sensor 98 will signal an alarm if unburnt hydrocarbons are passing through the output duct 100, causing a system shutdown to allow correction or alteration of the system parameters to ensure complete combustion of all combustible effluents. The combustion of the combustible effluents also destroys any pathogens which may be trapped therein and which had remained active before combustion.

In an alternative system, the radio frequency chamber 34, as may best be seen in FIG. 13, is connected

to an effluent output line 111 having electrical resistance heating elements 113 wrapped thereabout to maintain a high temperature of the output effluent, thereby preventing any heavy fractions from condensing 5 within the duct 111 and also sterilizing the effluents. Thermal insulation 114 is also wound about the heating elements 113 to prevent excessive heat loss from the electrical heating elements and also to prevent condensation of heavy fractions within the duct 111. An 10 air cooled vapor cooling system 116, which in the alternative may be water cooled, causes condensation of heavy fractions into liquid which may then be passed by a duct 18 to a demister 120. The demister 120 separates any remaining gas flowing through the duct 118 into a 15 gaseous fraction which is fed on a gas line 122, and a liquid fraction fed via a liquid line 124. A carbon adsorbent system 126 receives the gas from the line 122 and vents any inert gases left over through a line 128 which is connected to a venting blower 130. The venting 20 blower 130 feeds the remaining inert cleaned gases through an output duct 132 to the environment. Similarly, the liquids are fed via the duct 124 to a liquid adsorbent system 134 which is filled with a commercially available adsorbent material for water 25 cleaning, such as Filtrasorb from Calgon. As an added precaution, clean water is then fed via duct 136 to a pump 138 which passes the clean water through a pipe 140 to a sterilizer 142 which heats the water to 90°C. for sterilization. The sterilized water is fed via a duct 30 144 to a receiving container 146 which receives and stores it. The sterilized water may then be disposed of in an appropriate manner.

As may best be seen in FIG. 8, an alternative semicontinuous waste system 200 is shown therein, 35 utilizing the radio frequency system shown in FIG. 6. The semicontinuous waste sterilization system 200

includes a radio frequency waste treater 202 and a waste transport system 204. A radio frequency energy generator 206 is coupled to the radio frequency waste treating reactor 34. In operation, the radio frequency energy generator 206, which includes a control system 208 connected via a cable 210 to a radio frequency power source 212, generates radio frequency energy in response to control signals from the control 208 and feeds the radio frequency energy via a cable 214 to a matching network 216. The matching network 216 has a power delivery cable 218 connected to it which has an inner conductor 220 terminating at a field exciter 222 of a loop type or other suitable type. A dielectric plug 224 terminates an end of an insulating jacket 226 of the coaxial cable and mates with an upper wall 203 of the radio frequency waste treating reactor 34. The radio frequency waste treating reactor 202 also includes a bottom wall 232, an inlet wall 234, an outlet wall 236, and a pair side walls, one of which is shown as a first side wall 238. Coupled to the treatment chamber is an inlet wave guide below cutoff tunnel 240 which is substantially rectangular in cross section, connected at an inlet 242 to the reactor 34. The reactor 34 also includes an outlet 244 formed in the wall 236 to which is conducted an outlet tunnel 248 which comprises a radio frequency wave guide below cutoff. The system may also include an inert gas source as well as an effluent handling system as shown in FIG. 3, although for simplicity such are not shown in FIG. 8.

The conveyor system or waste transport system 204 includes an electric motor 250 controlled by signals carried on a cable 252 from the control 208. The motor 250 drives an input drum 252 of the conveyor system which in turn drive a conveyor belt 254. An output drum 256 also engages the belt 254 in a conventional fashion.

Pressure vessels 260 of the type which may best be seen in FIGS. 10, 11A, and 11B, are carried by the conveyor belt 254 through the inlet tunnel 240 into the radio frequency reactor 34. The pressure vessels 260 are substantially cylindrical in shape and include an inlet 262 terminating in a flange assembly 264 which receives a closure cap 266. The closure cap 266 seats against an O-ring or gasket 268 for a gas tight seal therewith. The O-ring 268 is also trapped against the flange 264. The cap 266 is held in compressive engagement with the O-ring by a plurality of bolts 270. The pressure vessel 260 includes a wall 272 which may either be completely transparent to radiofrequency radiation, or be deliberately absorbent to heat the wall by the radio frequency energy such that the wall temperature approximates that of the material being heated. Alternatively, the interior portion of the wall of the container may be thermally insulating to achieve the same purpose. The pressure vessel 260 is preferably made using fiberglass reinforced high temperature epoxies or equivalent plastic material to withstand the temperatures and pressures needed for sterilization. A plurality of waste bags 276 are held in the interior 278 of the pressure vessel 260 for heating by the radio frequency energy as was set forth above.

A plurality of thermocouple openings 280 are provided in an upper portion of the vessel so that, if desired, temperature readings may be made of the interior of the vessel 260 to assure a minimum of 90°C. A pair of pressure relief valves 282 are also included. The pressure relief valves are rated at about 15 psi, that is, they remain closed until the internal pressure of the vessel 260 exceeds the external pressure by 15 pounds per square inch. This allows vapor to be contained even if the medical waste 16 is heated above 100°C., the boiling point of water at atmospheric pressure. It also allows

the waste or medical materials to be heated to 120°C. without vaporizing most of the water within the bags. The release valves 282 are provided in order to protect the operators of the system from overpressure within the pressure vessels 260. Should it be necessary to inject additional water into the pressure vessel 260, a water injection port 288 is provided in the wall of the vessel. A rupture disk 290 is also provided in the vessel 260 to prevent excessive buildup of pressure in the event of failure of the pressure release valves 282. An optional sterilized waste port 292 is provided as an aid for pushing medical waste from the pressure vessel 260 following sterilization with the radio frequency energy.

The pressure vessel 260 also includes gear cogs 300 arranged around the neck 262 of the inlet of the pressure vessel 260. When the pressure vessel 260 is transported into the radio frequency heating chamber 34, the drive gear box 304 and mounting assembly 301 are normally below the bottom surface 232 of the reactor 34. To rotate the vessel, the drive gear 304 and the mounting assembly 301 are raised so that the drive gear 304 engages the cog 300 to rotate the pressure vessel so that all bagged medical waste within the pressure vessel 260 is exposed to all three time-varying vectors of the electromagnetic field to further ensure complete electric field exposure and uniform heating.

In an alternative embodiment the pressure relief valves can be left off the pressure vessel and the vessel can be used solely as a waste bag container for transportation through the system. For this atmospheric pressure embodiment it is important that the large pressure vessel also be rotated to eliminate the possibility of shaded areas, as previously discussed. Thus, by this method, all parts of the waste material are exposed to substantial levels of electric fields with a

resultant possibility of achieving lower temperature sterilization by the combined or collateral effects of temperature and electric fields. In practice, the material in the temperature vessel first is heated to the vaporization point of water as in the case for the system shown in FIG. 3. The dry, relatively poorly absorbing material receives water vapor from the moist material and thereby becomes more absorbing to realize an almost equal temperature rise of the wet and dry material within the bags. At this point a minimum temperature in the bags of 90°C. may be realized. Then the bags and the boxes are removed through the exit tunnel and heat soaking arrangement as previously described for the 90°C. or more heat soaking system, except that the heat soaking temperature in this case of 100°C. may be preferred.

Alternatively, it may be desirable to further heat the material at atmospheric pressure to temperatures of about 100 or 120°C. This may be done by further application of the time varying electric fields such that the material is dehydrated nearly completely and a minimum temperature of 100 or 120°C. is realized through dielectric heating.

In many cases, especially if pressurization at near atmospheric levels is employed and if heating beyond the vaporization temperature of the dry material is required, the total energy or "dose" applied to the waste must be controlled. Energy should be sufficient to accomplish the desired final temperature with some additional safety margin. This may result in some of the material being overheated beyond the desired final temperature of approximately 120°C. However, too little energy can result in underheating some portions of the material and too much energy can result in excessive energy consumption along with partial or complete pyrolysis of the waste. Excessive waste also generates noxious gases and thereby burdens the effluent treatment system.

To mitigate these problems, as shown in FIG. 8 sensors 237a and 238b are used to determine the moisture content and/or the presence of sharps. Previously the material may have been weighed and the weight data supplied to the control unit 208 via a cable 239. The control unit then programs the exposure level and controls this via the electric field sensor 234 and the duration of the exposure by sequentially activating the belt 254 via a line 252 and a motor 250. A sensor 237d remotely monitors the temperature of the material in the vessel 260 by monitoring the infrared or longer wavelength electromagnetic emissions from the material being heated. The Sensor 237e monitors the gaseous effluent so as to limit excessive pyrolysis.

Additional wall insulation and/or wall heating may also be employed to suppress heat losses due to convection and diffusion. This is especially desirable if heating above the vaporization temperature is needed. Additional wall and panel insulation 241 along with a wall and a panel heater 343 may be employed. The wall and panel heater are also controlled by the control system 208.

For those cases where heating above the vaporization point of water is employed, it is especially important that the chamber be filled with an inert gas such as nitrogen. The means for the injecting the nitrogen in and keeping the oxygen out are described for the system shown in FIG. 3. For the semicontinuous system shown in FIG. 8, less care is needed in controlling the direction of sweep gases. However, if a continuous version of FIG. 8 is employed, the direction of sweep gases should be from the cooler material to the hotter material as discussed in the embodiment shown in FIG. 3.

The pressure vessel may then be carried, after treatment by the radio frequency energy, to the outlet

tunnel 248 where electrical resistance heaters 306 provide heat soaking to the pressure vessel 260, holding it at the desired temperature for a specified period of time in order to provide extra assurance of the 5 destruction of pathogens in the infectious medical waste.

Details of a radio frequency feed structure for the cavity resonator 32 may best be seen in FIGS. 6A, 6B and 6C. The cavity resonator 32 may in an alternative embodiment be fed from opposite sides by loop type 10 excitors 310 and 312. The loop exciter 310 is driven at a frequency of 40.68 megahertz while the loop exciter 312 is driven at twice that frequency, 81.36 megahertz. It may be appreciated that this arrangement allows a highly uniform average power to be present within the cavity. 15 As may best be seen in FIG. 7A, a cavity having standing waves induced therein at the lowest mode, has an average power density with a peak at the center of the cavity. If the cavity is driven at a frequency of 81.36 megahertz a pair of power peaks occur, as may be seen in FIG. 7B. 20 The continued effect of the two feeds of the twin feed cavity shown in FIGS. 6A through 6C is shown in FIG. 7C with the power density curve for a relative amplitude for power of 0.864 at the fundamental 40.68 megahertz frequency and a relative amplitude of 0.48 at the first 25 octave or 81.36 megahertz frequency, thereby providing a highly uniform power across three quarters of the distance across the cavity as shown in FIG. 7C. This further provides uniform heating for the medical waste 16 within the cavity.

30 A detailed flow chart of the process steps carried out by the apparatus and method of the present invention is shown in FIG. 9. In step 400, the medical waste is received at a receiving bay and transferred to a belt conveyor in step 402. Optionally, in step 404, the 35 waste 16 may be appropriately identified by bar coding or any other identification method and may be sorted.

according to bagged waste into lightweight boxes in step 406, heavy and liquid waste boxes in step 408, sharps containers in step 410 and possibly cardboard in step 412. Optionally, the waste may be repacked in processing 5 containers such as additional boxes of corrugated material in step 414 and then is further transferred by conveyor to a radio frequency heating system in step 416. The waste may be restacked and optional temperature validation procedures may be carried out in step 418.

10 The waste is then segregated in step 420. Sterilized sharps containers are fed to a shredder for sharps containers in step 422. Other material is fed to a shredder for general waste in step 424. The waste may be optionally separated in step 426. Plastic may be sent 15 to a polypropylene storage tank in step 430 and other material may be sent to fuel storage facility 428. Sterilized cardboard may be recycled in step 432.

Preliminary to the use of the present invention, medical waste arrives at a processing and recycling facility. Preferably the material is shipped 20 in sealed containers, usually sealed plastic bags. The plastic of the bags does not significantly absorb the radio frequency energy with which the medical waste is treated. This means of shipping medical materials is known in the art and has the advantage that the medical 25 waste does not infect or contaminate its handlers in transit.

The pallets remain in the heating chamber and receive radio frequency waves for a sufficient time to 30 raise the temperature of the medical materials to approximately 85 to 125°C. It will be recognized by those skilled in the art that temperatures as high as 170°C. may be employed without adversely affecting the material to be sterilized. In the disclosed embodiment, 35 the medical waste 16 is moved through the radio frequency treatment unit 12. The total dose of radio frequency

energy to which the medical waste 16 is exposed during its dwell time in the unit 12 is planned to provide sufficient sterilization.

Preferably, a medical material sterilization facility using the present invention is validated to assure the adequacy of the sterilization process. Validation may be performed when each facility is constructed and at intervals during its operation. Validation may consist of placing heat detecting devices such as thermocouples, resistance temperature detectors, or the like, and/or known amounts of particular microorganisms which are resistant to heat into a pallet load of medical materials. Sufficient radio frequency energy is applied to raise the temperature of a sterilizer's load to about 85 to 125°C. If thermocouples are used, they should all record at least 85°C. indicating that all portions of the load have been heated to at least 85°C. and that there are no cold spots where microorganisms might survive. After the entire sterilization cycle is complete, the microorganism samples are removed from the pallet and cultured by being given nutrients and other appropriate conditions for growth in order to determine whether any have survived the radio frequency energy treatment. A typical heat resistant microorganism which may be used in validation of the sterilization process is Bacillus stearothermophilus. If more than one in ten thousand of any microorganism survives the exposure to radio frequency energy, the exposure must be increased and another pallet tested, and the previously tested pallet must be retreated with radio frequency energy. On retest, a temperature of 92C may be tried. If that is not adequate, further retests at 94, 96, and 98C may be undertaken until the necessary kill rate is obtained.

The pallets are held in the radio frequency chamber and exposed to radio frequency waves for a

sufficient time to raise the temperature of the medical materials to at least approximately 85°C. It will be recognized by those skilled in the art that temperatures as high as 170°C. will not adversely affect the process.

5 Preferably, the exposure time to radio frequency waves will vary depending upon the radio frequency power and the weight of material in order to elevate the temperature of the medical materials to 85 to 125°C. and hold that temperature for up to 45 minutes as an extra 10 margin of safety, assuring an even higher kill rate. However, the optimal exposure time to the radio frequency waves and the field strength of the electromagnetic field of the time-varying field for a particular facility will vary and may be determined as described above.

15 In a still further embodiment, the sterilizer load may consist of 18 inch by 18 inch boxes loaded with polyethylene bags filled with hospital waste containing approximately 5 to 10 percent water by weight. In a further embodiment the sterilizer load may consist of 18" 20 x 18" boxes loaded with polyethylene bags filled with shredded hospital waste. Inside each such box an envelope containing test strips loaded with 1×10^6 spores of Bacillus subtilis, var. niger. may be employed. Thermocouple temperature probes also may be 25 placed within and around the boxes.

Another embodiment of the invention consists of starting with medical or veterinary waste that has been presorted into containers of plastic and general medical waste, respectively. High grade plastics are employed in 30 medical products and can be shredded and molded into a variety of other products. This waste is subjected to radio frequency energy and the containers of sterilized waste are moved to a shredder for the plastics. For example, an electrically powered shredder having a 35 pneumatic ram assist with a negative pressure canopy can shred the medical waste to small particles. Such a

shredder may be purchased from Shredding Systems, Inc. of Wilsonville, Oregon, and is identified as a model Dual 1000 E. The negative pressure air canopy removes odors and particles entering the surrounding air and
5 contaminating the atmosphere. The odorous air is then scrubbed and particulates removed by impact filters or electromatic precipitators. The containers or medical waste bags are opened and the sterilized plastic is placed in the shredder and shredded to particles of about
10 one-quarter to one-half inch mean linear dimension. The sterilized shredded plastic is transferred to 55 gallon drums for shipment to plastic recyclers.

Likewise, the containers of sterilized general medical waste may be placed in a general medical waste
15 shredder. After the containers are opened, the sterilized general medical waste is placed in the shredder and shredded to particles have a mean linear dimension of one-quarter to one-half inch. The sterilized waste is placed in further containers
20 containing a mixture of paper, plastic, and metal, which can be used as fuel. Possible users include cement kilns which burn fuel to create temperatures of about 130°C. or more and which might otherwise employ high sulfur coal. Because the general medical waste is low in sulfur, its
25 use as fuel will not generate sulfur compounds which might be released into the atmosphere and contribute to acid rain.

It is believed that part of the superior effectiveness of the radio frequency heating method
30 disclosed herein is due to the fact that radio frequency electromagnetic energy penetrates large boxes and volumetrically heats the contents thereof very efficiently. However, this factor alone is not believed to account entirely for the difference observed. It is
35 further believed that the efficacious results of the instant process may be due to the fact that bacteria and

viruses have a much higher water content than most of the mixed medical waste. As a result, the relatively high dielectric constant of the bacteria and viruses efficiently couples the electromagnetic or time-varying electromagnetic field energy to the water, causing rapid heating of the microorganisms and subsequent inactivation or destruction thereof. Substances with high dielectric constants selectively absorb radio frequency energy.

5 Therefore, radio frequency energy may heat the bacteria and viruses to a lethal temperature before the surrounding waste reaches what is generally considered a lethal temperature.

10

15 Individually, the boxes were placed in a two-plate 40KW radio-frequency heating chamber. The radio-frequency was 18 megahertz. The following parameters were used:

	Plate KV	=	13KVDC
20	Plate Amps	=	0.5 Amps (No Load) to 0.8 Amps (Loaded)
	Grid Amps	=	0.4 - 0.6 Amps
	Electrode Height	=	9.75" (Approximately 1" above box)
	Time	=	57 Minutes
25	Temperature	=	108 C (maximum internal)

At the end of the run, the load was allowed to cool. The boxes and individual bags were opened and the spore strips were removed and cultured according to standard techniques. For one run, of thirteen strips, four showed no growth at all. For the nine viable strips, the D-value, or amount of time needed to kill 90% of a test dose, was calculated. For RF, at a maximum temperature of 108C, the D-value was approximately 9 minutes.

30

As a control, a dry heat test vessel was used to determine the D-values for Bacillus subtilis, var. niger spore strips at 149, 160, and 179C. These D-values

35

were graphed and extrapolated to 108C. At a temperature of 108C the D-value for the dry heat process was 20 minutes. Therefore, at a temperature of 108C the D-value of 9 minutes for the RF treatment was less than half of the dry heat value. This is evidence that RF heating is markedly more efficient than is the dry heat process, in that it yields a comparable microbial kill rate in significantly shorter time.

At 121C, the D-value for the RF heating process was 0.31 minutes. A control test of dry heat yielded no kill at this time at any temperature. At 121C, RF was markedly more effective than the dry heat process.

The foregoing descriptions of the preferred embodiments of the present invention have been presented for purposes of illustration and description. They are not intended to be exhaustive or to limit the invention to the precise forms disclosed, and obviously many other modifications and variations are possible in light of the aforementioned teachings. The embodiments were chosen and described to best explain the principles of the invention and its practical applications, thereby enabling others skilled in the art to utilize best the invention in its various embodiments and with various modifications as are suited to the particular use contemplated.

WHAT IS CLAIMED IS:

1. A method of sterilizing medical materials comprising heating the medical materials to a temperature of 85 to 125°C. by the use of radio frequency waves.

2. A method of sterilizing medical materials as defined in claim 1, wherein the step of heating with radio frequency waves comprises heating with radio frequency waves having a frequency in the range of approximately 500 kilohertz to 600 megahertz.

3. A method of sterilizing medical materials as defined in claim 1, wherein the step of heating with radio frequency waves comprises heating with radio frequency waves having a frequency in the range of approximately 15 megahertz to about 100 megahertz.

4. A method of sterilizing medical materials as defined in claim 1, wherein the step of heating with radio frequency waves lasts for a duration of at least approximately 5 minutes.

5. A method of sterilizing medical materials as defined in claim 1, wherein the step of heating with radio frequency waves lasts for a duration of between approximately 3 and 50 minutes.

6. A method of sterilizing and processing heterogeneous medical waste, comprising the steps of:
30 applying a radio frequency electric field to heterogeneous medical waste to heat the heterogeneous medical waste to a temperature of 85 to 125°C. to produce sterilized medical waste;

35 comminuting the sterilized medical waste into comminuted waste particles; and
recycling the comminuted waste particles.

7. A method of sterilizing and processing heterogeneous medical waste as defined in claim 6, wherein the step of comminuting the sterilized medical waste comprises reducing the sterilized medical waste to 5 comminuted waste particles in a size range of approximately one-quarter to one-half inch.

8. A method of sterilizing and processing heterogeneous medical waste as defined in claim 6, 10 further comprising, prior to applying the radio frequency electric field, the step of sorting the heterogeneous medical waste into plastics and general medical waste and placing the plastics and general medical waste into separate processing containers for plastics and general 15 medical waste, respectively.

9. A method of sterilizing and processing heterogeneous medical waste as defined in claim 8, 20 wherein the recycling step for presorted medical waste comprises reusing the plastic and using the general medical waste as fuel.

10. A method of sterilizing and processing heterogeneous medical waste as defined in claim 8, 25 wherein the step of applying the radio frequency electric field comprises applying a radio frequency electric field having a frequency in the range of approximately 500 kilohertz to 300 megahertz.

30 11. A method of sterilizing and processing heterogeneous medical waste as defined in claim 6, 35 wherein the step of applying the radio frequency electric field comprises applying a radio frequency electric field having a frequency in the range of approximately 1 megahertz to 100 megahertz.

12. A method of sterilizing and processing heterogeneous medical waste as defined in claim 6, wherein the step of applying the radio frequency electric field lasts for a duration of at least approximately 5 minutes.

13. A method of sterilizing and processing heterogeneous medical waste as defined in claim 6, wherein the step of applying the radio frequency electric field lasts for a duration of between 10 approximately 3 and 30 minutes.

14. A method of sterilizing and processing heterogeneous medical waste as defined in claim 6, wherein the step of applying the radio frequency electric field employs a radio frequency electric field having a frequency of about 18 megahertz for a duration of between 15 approximately 3 and 30 minutes and heats the heterogeneous medical waste to a maximum 20 of about 100°C.

15. A method of rendering heterogeneous medical waste innocuous comprising the steps of:

25 confining a quantity of heterogeneous medical waste comprising wet portions and dry portions in a closed treatment container;

30 exposing the treatment container to a time-varying electric field to evaporate water from the wet portions of the medical waste, transporting the resulting water vapor by convection and diffusion to dry portions of the heterogeneous medical waste, condensing some of said water vapor on cooler dry portions, reheating the condensed water by the persisting 35 time-varying electric field, transferring heat by thermal conduction to the previously dry portions of the

- 48 -

heterogeneous medical waste which the water contacts so that all portions of the heterogeneous medical waste are substantially uniformly heated by the time-varying electric field.

5

16. A method of rendering heterogeneous medical waste innocuous as defined in claim 15, further comprising the step of comminuting the sterilized medical waste into comminuted waste.

10

17. A method of rendering heterogeneous medical waste innocuous as defined in claim 15, further comprising the step of heat soaking the heated medical waste for a period of about 30 minutes.

15

18. A method of rendering heterogeneous medical waste innocuous as defined in claim 15, wherein the treatment container confines the evaporated water at substantially greater than ambient pressure whereby the water is heated above 100°C. to allow the heterogeneous medical waste to be heated above 100°C.

20
25

19. A method of rendering heterogeneous medical waste innocuous as defined in claim 15, wherein the frequency of the radio frequency electric field is less than the frequency of microwaves.

20. An apparatus for rendering infectious medical waste innocuous comprising:

30

a radio frequency treatment unit for accepting medical waste to be treated;

means for transporting infectious medical waste in closed bulk containers through the radio frequency treatment unit; and

35

- 49 -

means for energizing the radio frequency treatment unit with a time-varying electric field having a frequency below the frequency of microwaves.

5 21. An apparatus for treating medical waste as defined in claim 20, further comprising means for soak heating treated medical waste after it exits the radio frequency treatment unit.

10 22. An apparatus for treating infectious medical waste as defined in claim 20, further comprising means for rotating the medical waste with respect to the time-varying electric field to provide more uniform exposure of the medical waste to the time-varying 15 electric field.

20 23. An apparatus for treating medical waste as defined in claim 20, further comprising means for injecting inert gas into the radio frequency treatment unit to sweep oxygen therefrom to avoid oxidizing heated medical waste and to cause a flow of gas from a relatively cool portion of the radio frequency treatment unit to a relatively warm portion to prevent any vapor which might have escaped from the medical waste from 25 condensing on cooler medical waste entering the radio frequency treatment unit.

30

35

1/12

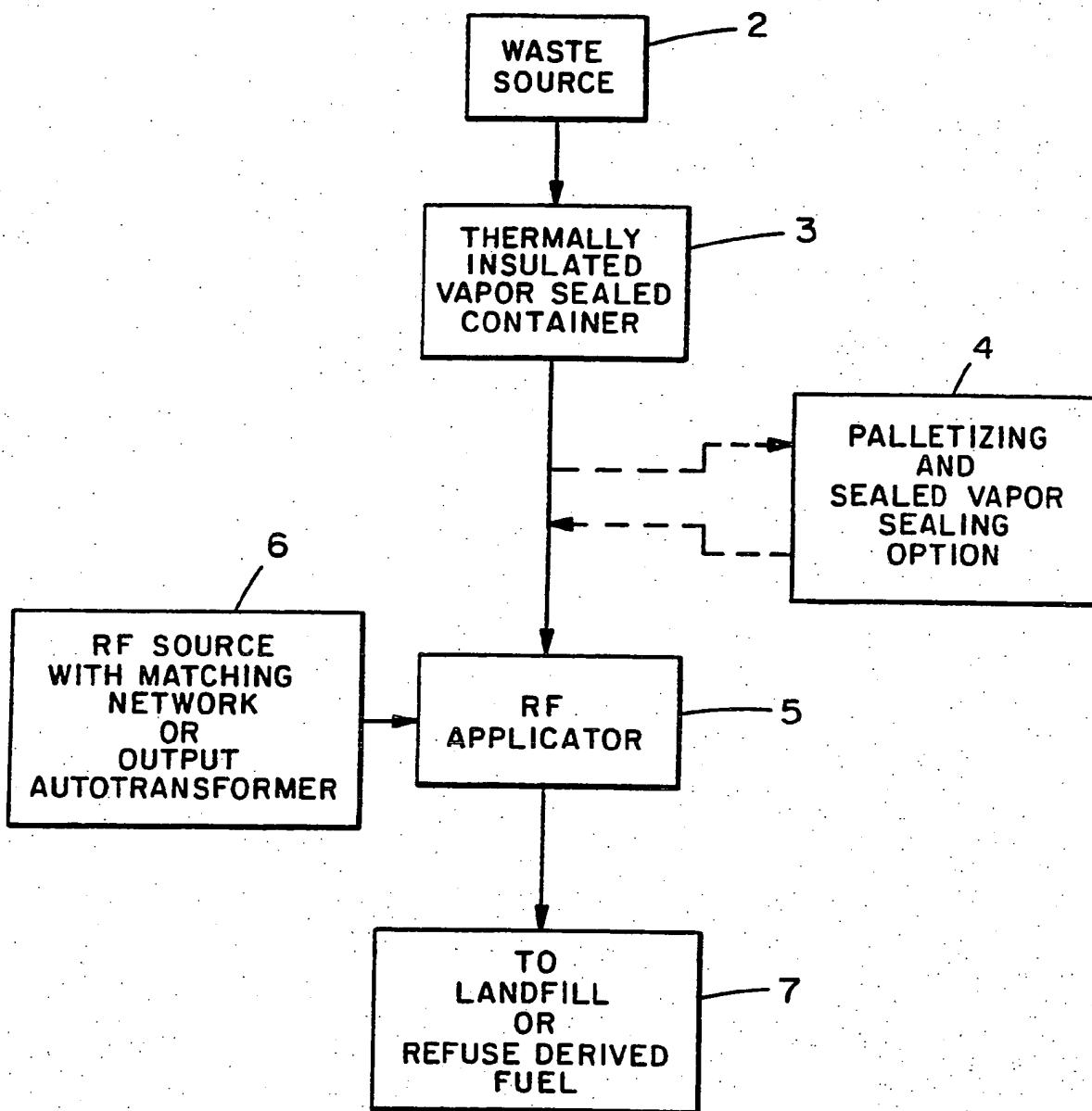


FIG. I

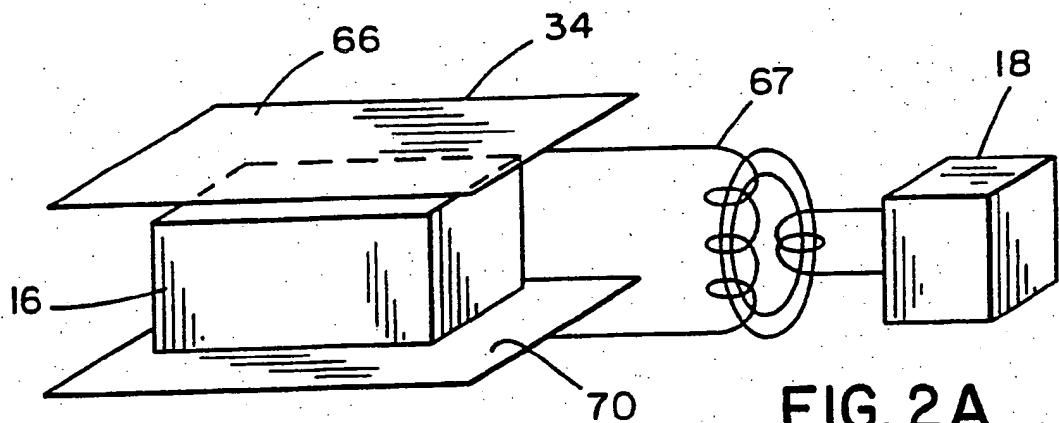


FIG. 2A

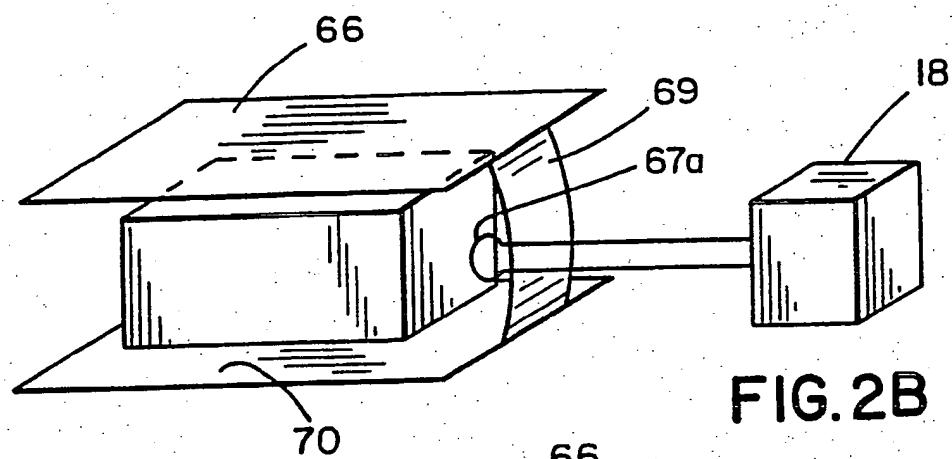


FIG. 2B

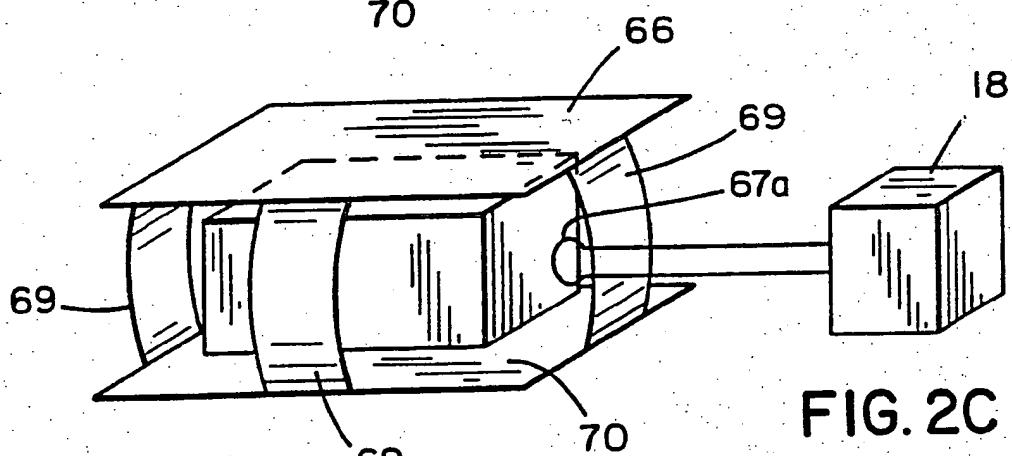


FIG. 2C

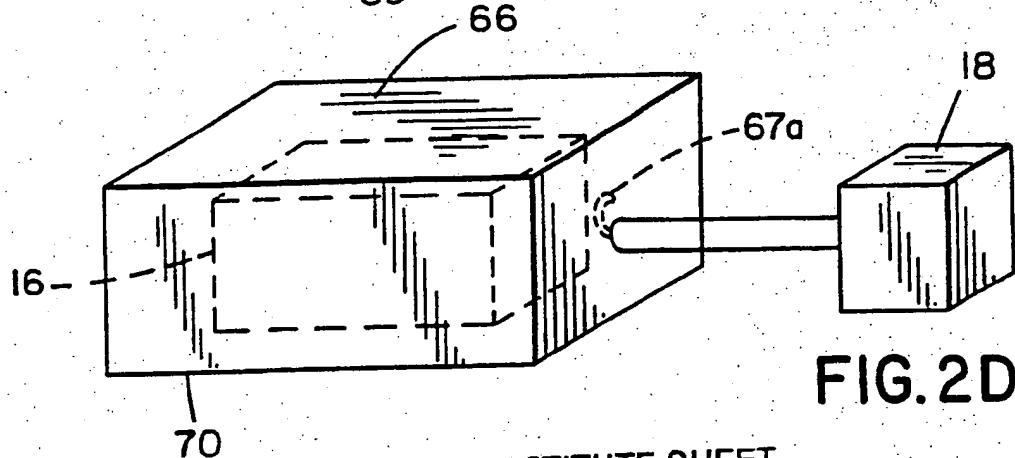
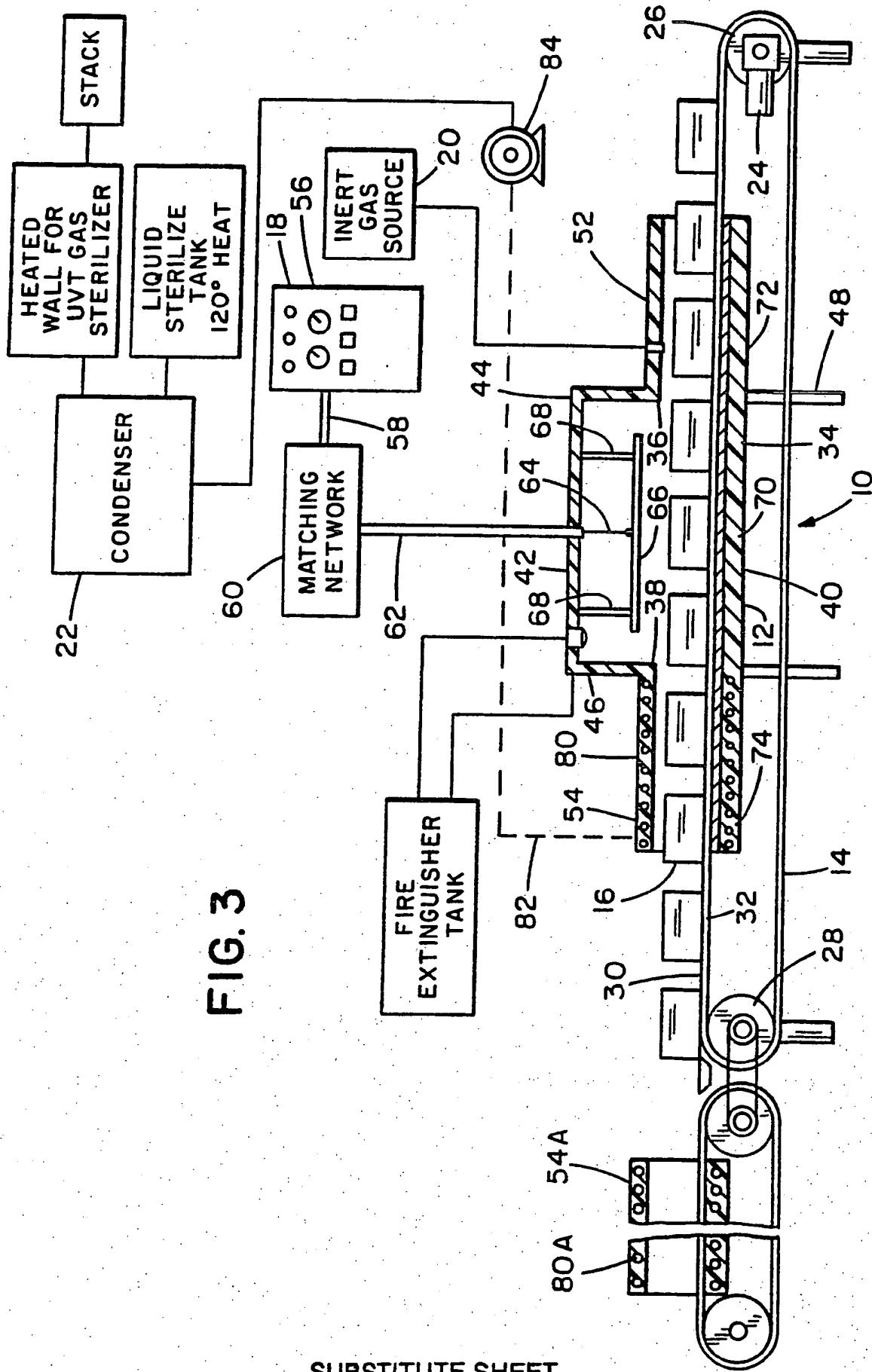
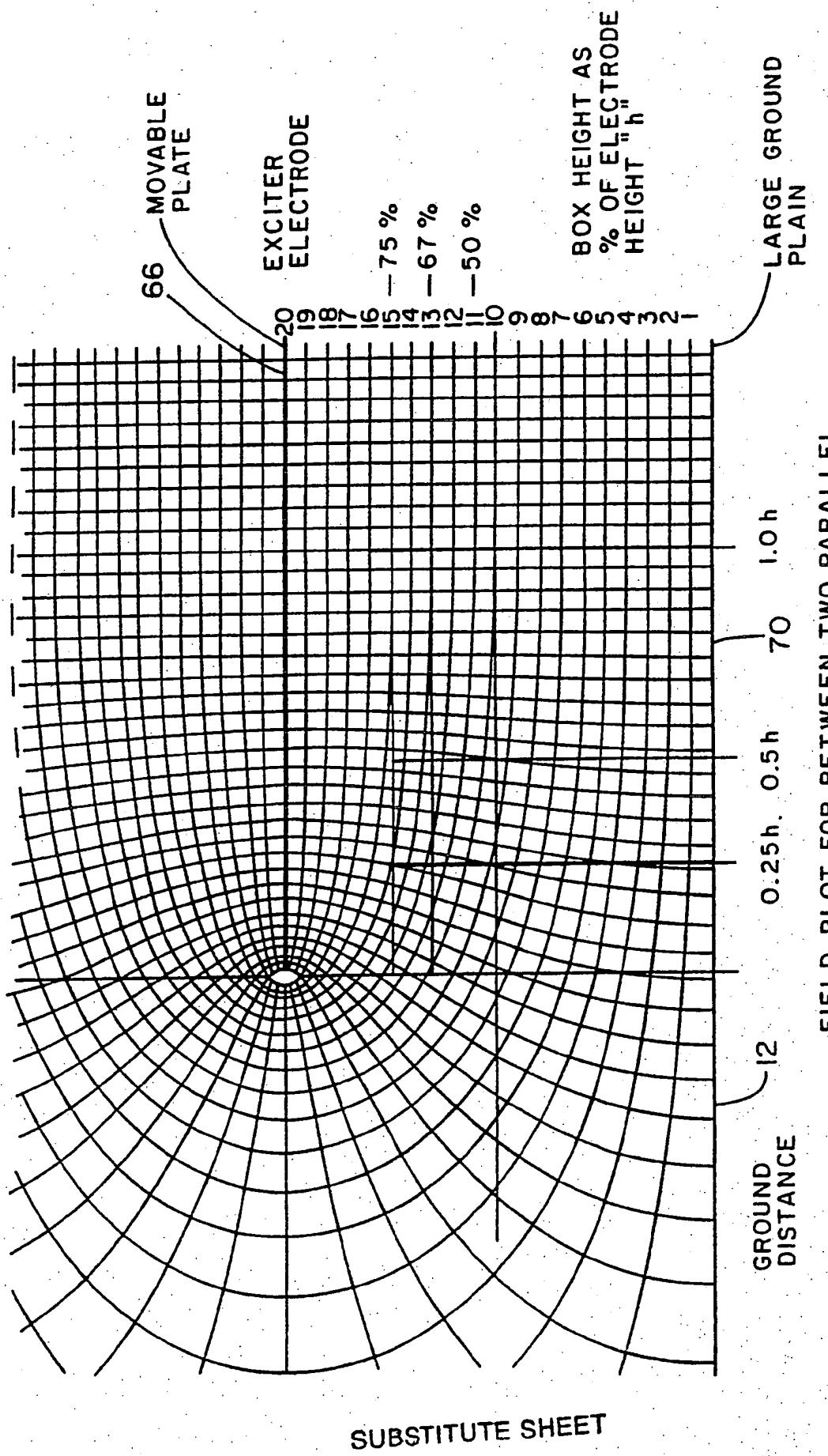


FIG. 2D

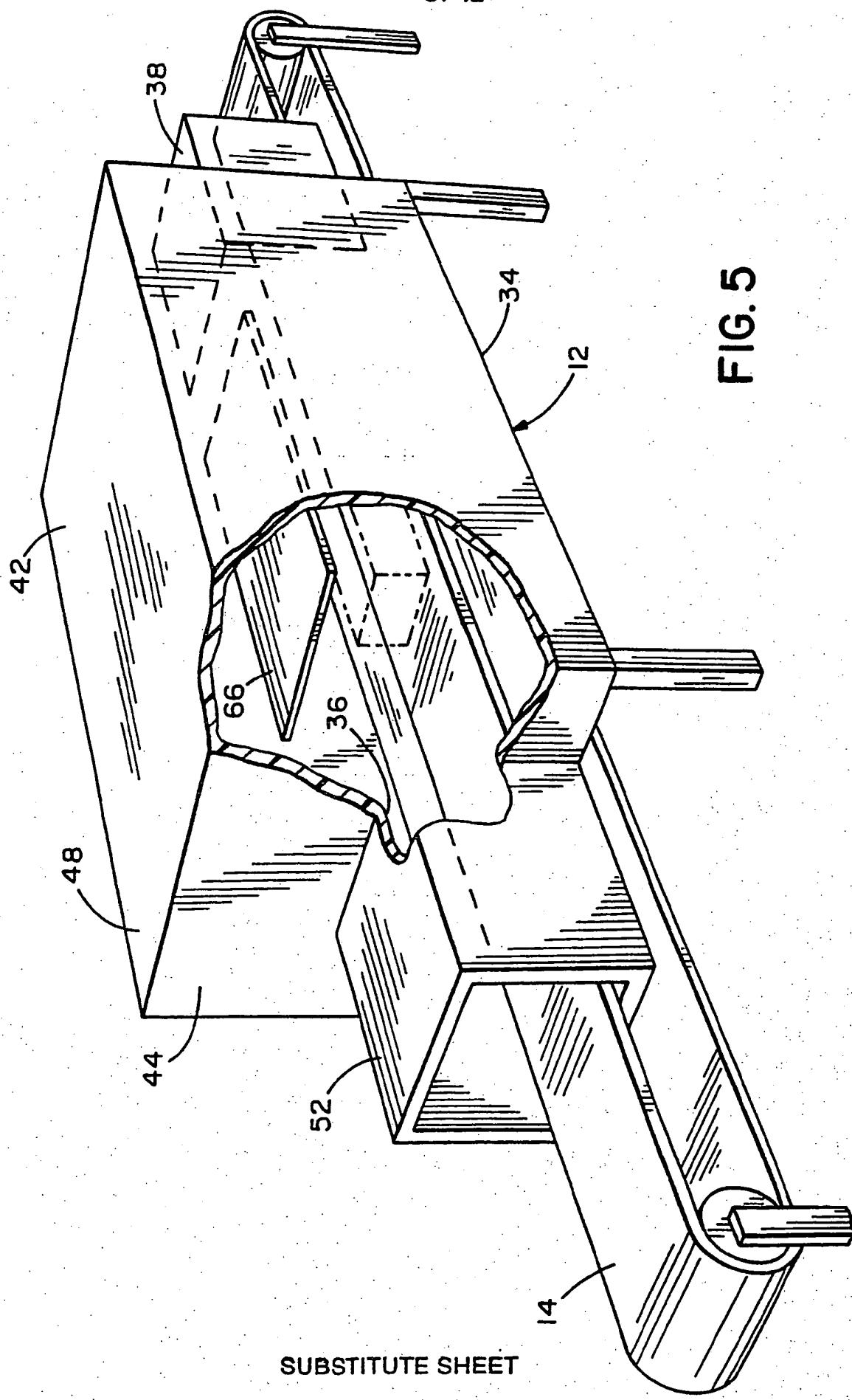
3/12

**FIG. 3****SUBSTITUTE SHEET**



FIELD PLOT FOR BETWEEN TWO PARALLEL
EXCITER ELECTRODE INFINITE
GROUND PLAINS

FIG. 4



SUBSTITUTE SHEET

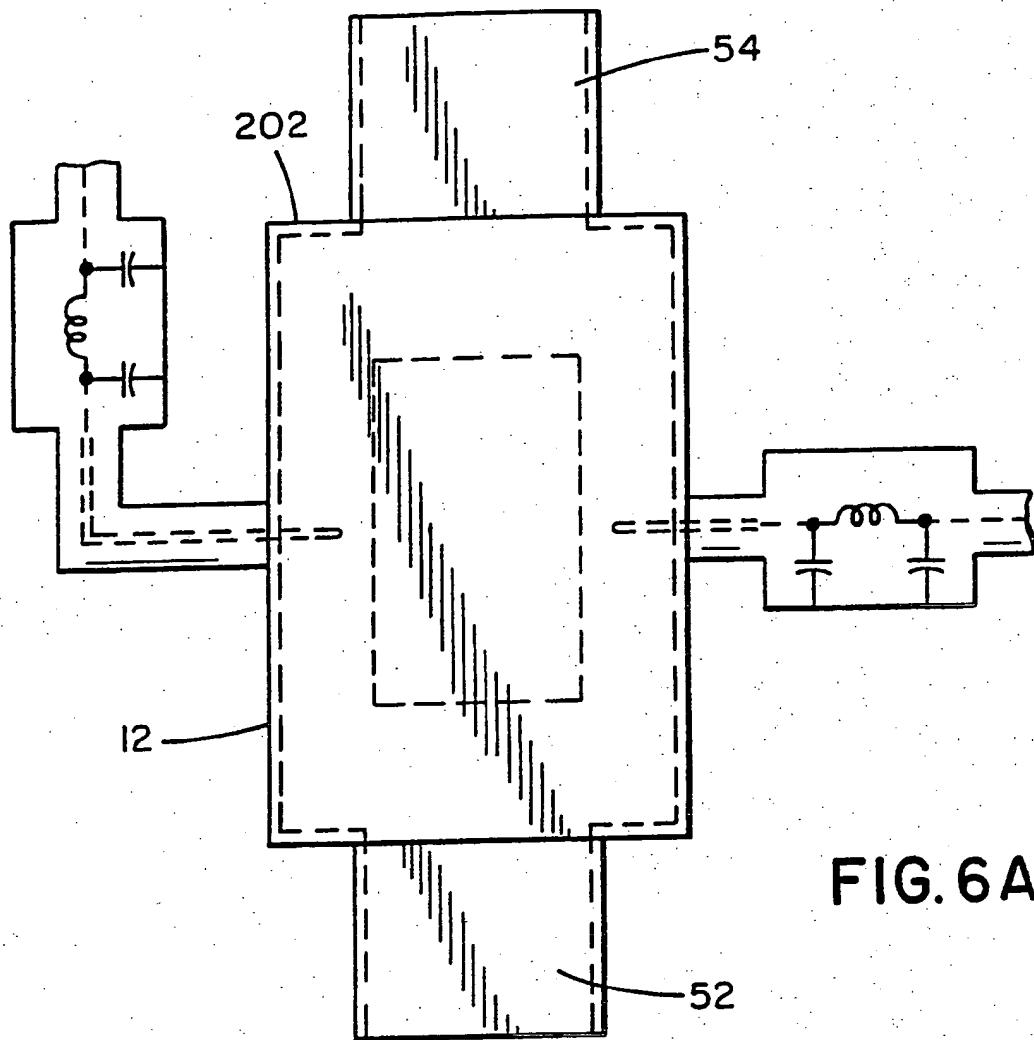


FIG. 6A

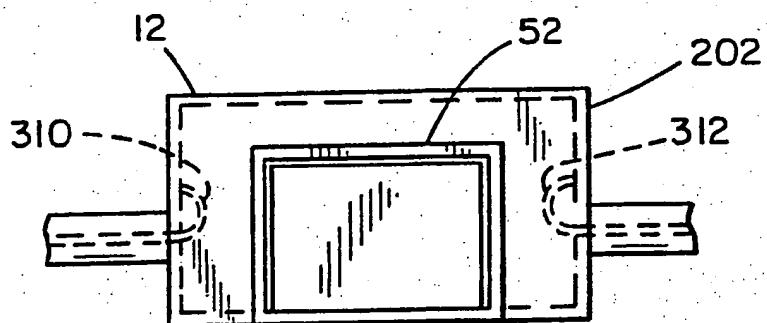


FIG. 6B

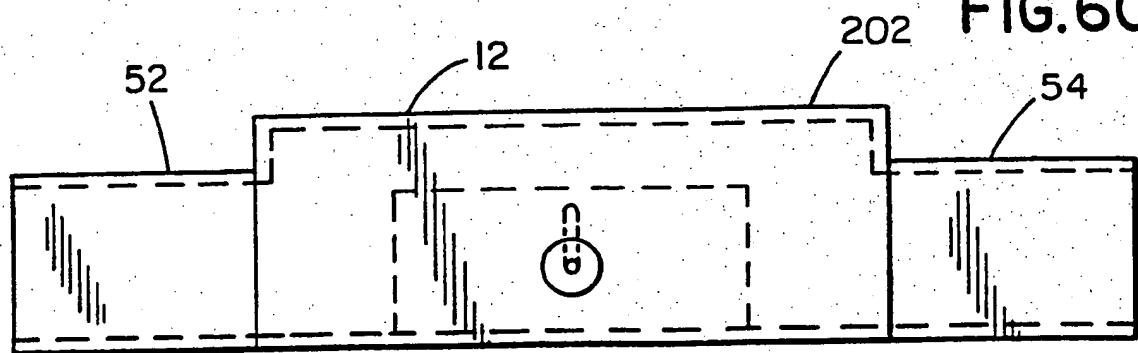


FIG. 6C

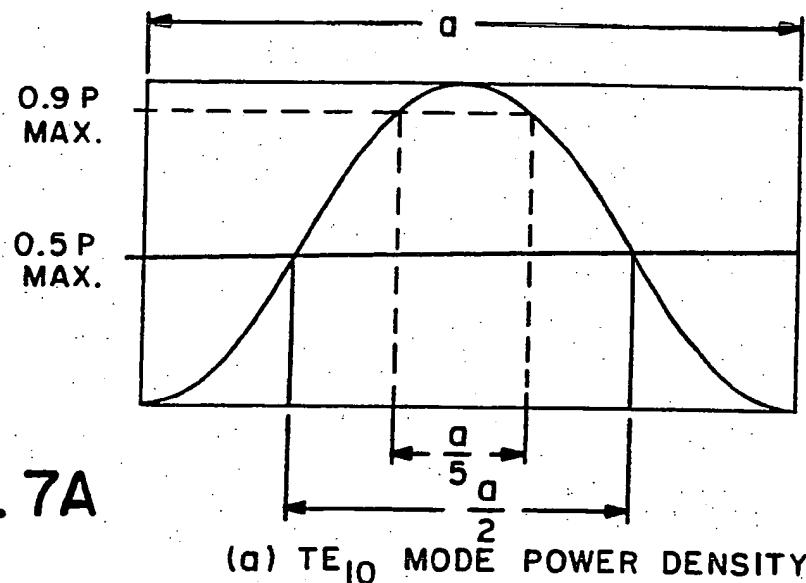


FIG. 7A

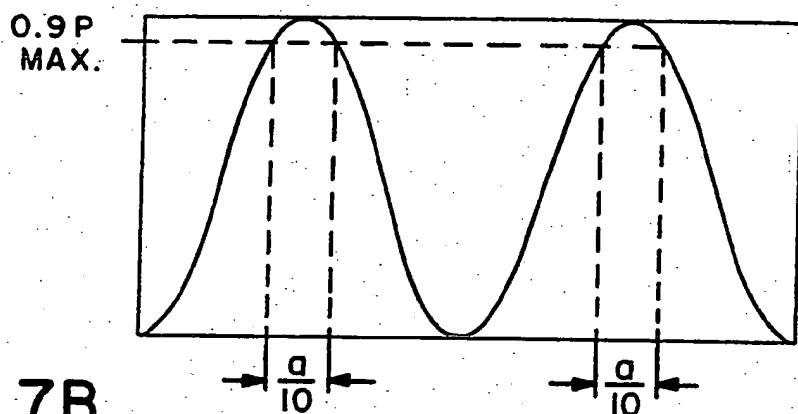
(a) TE_{10} MODE POWER DENSITY

FIG. 7B

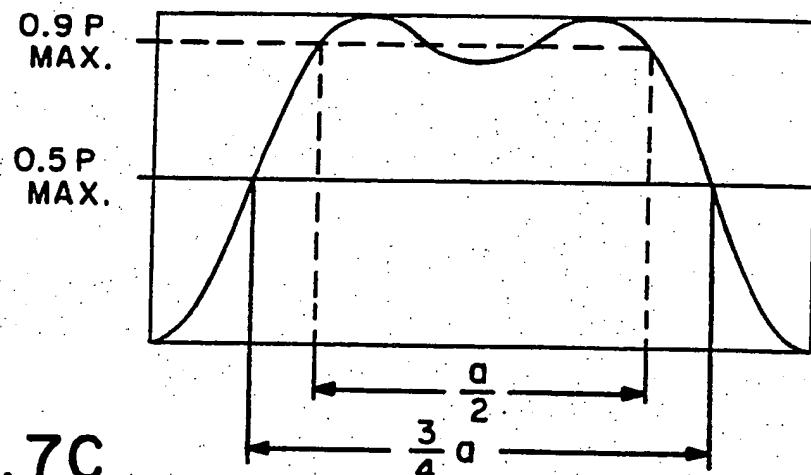
(b) TE_{20} MODE POWER DENSITY

FIG. 7C

(c) $0.864 TE_{10} + 0.48 TE_{20}$ POWER DENS

8
E/G

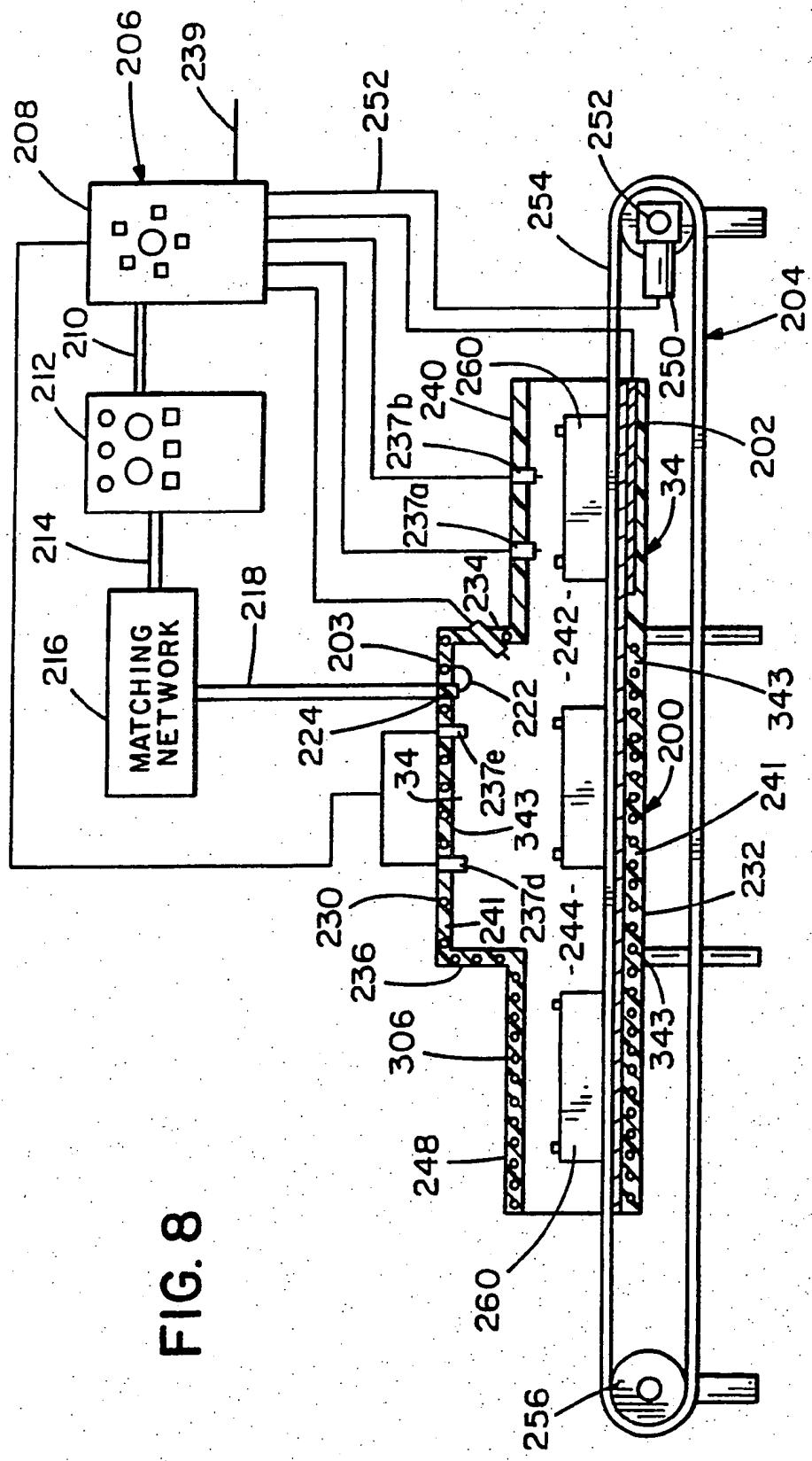
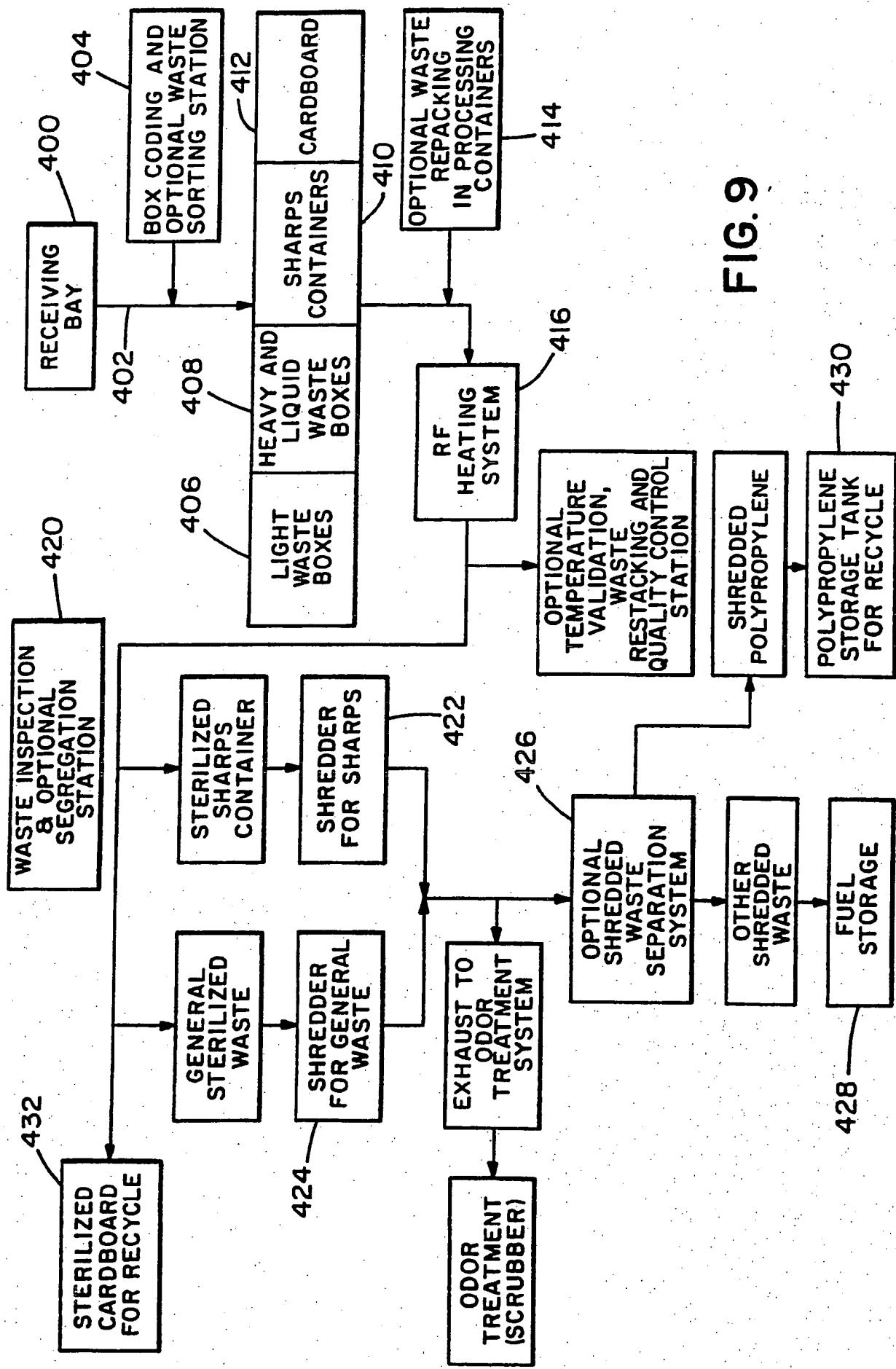
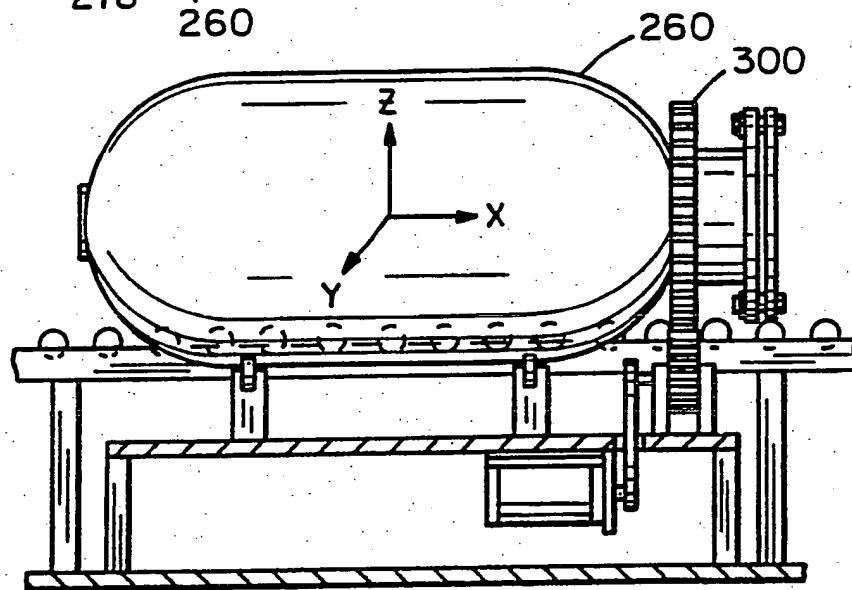
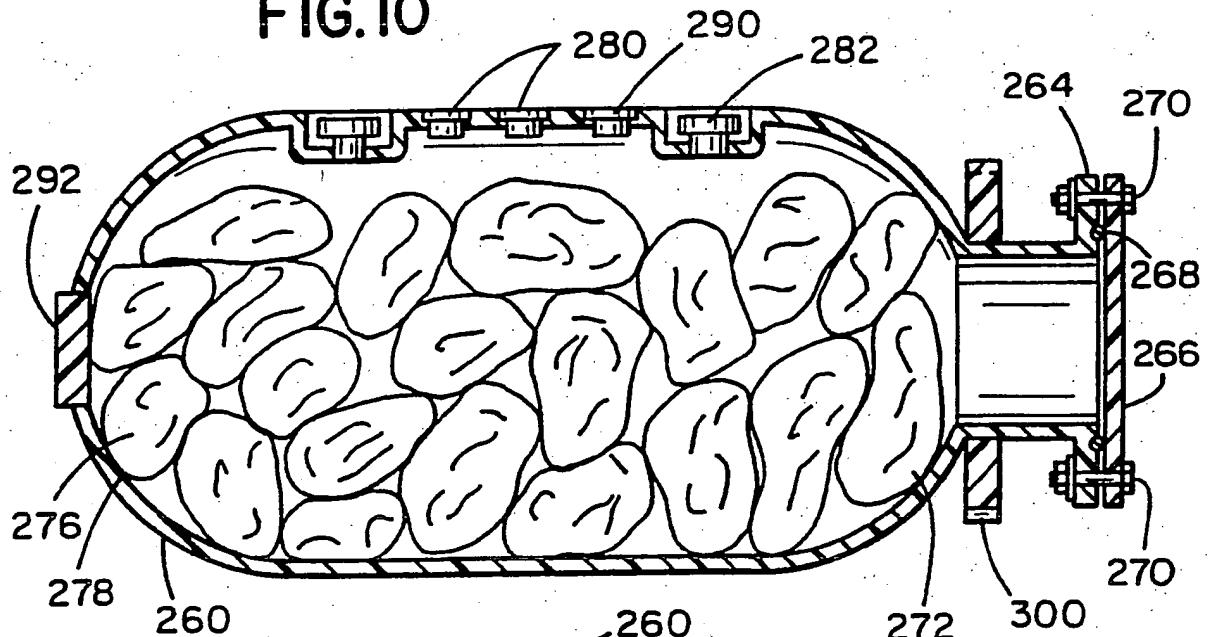
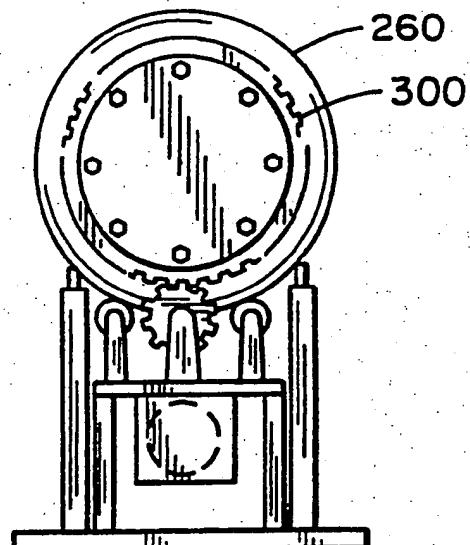


FIG. 9



SUBSTITUTE SHEET

FIG. 10**FIG. 11A****FIG. 11B**

11/12

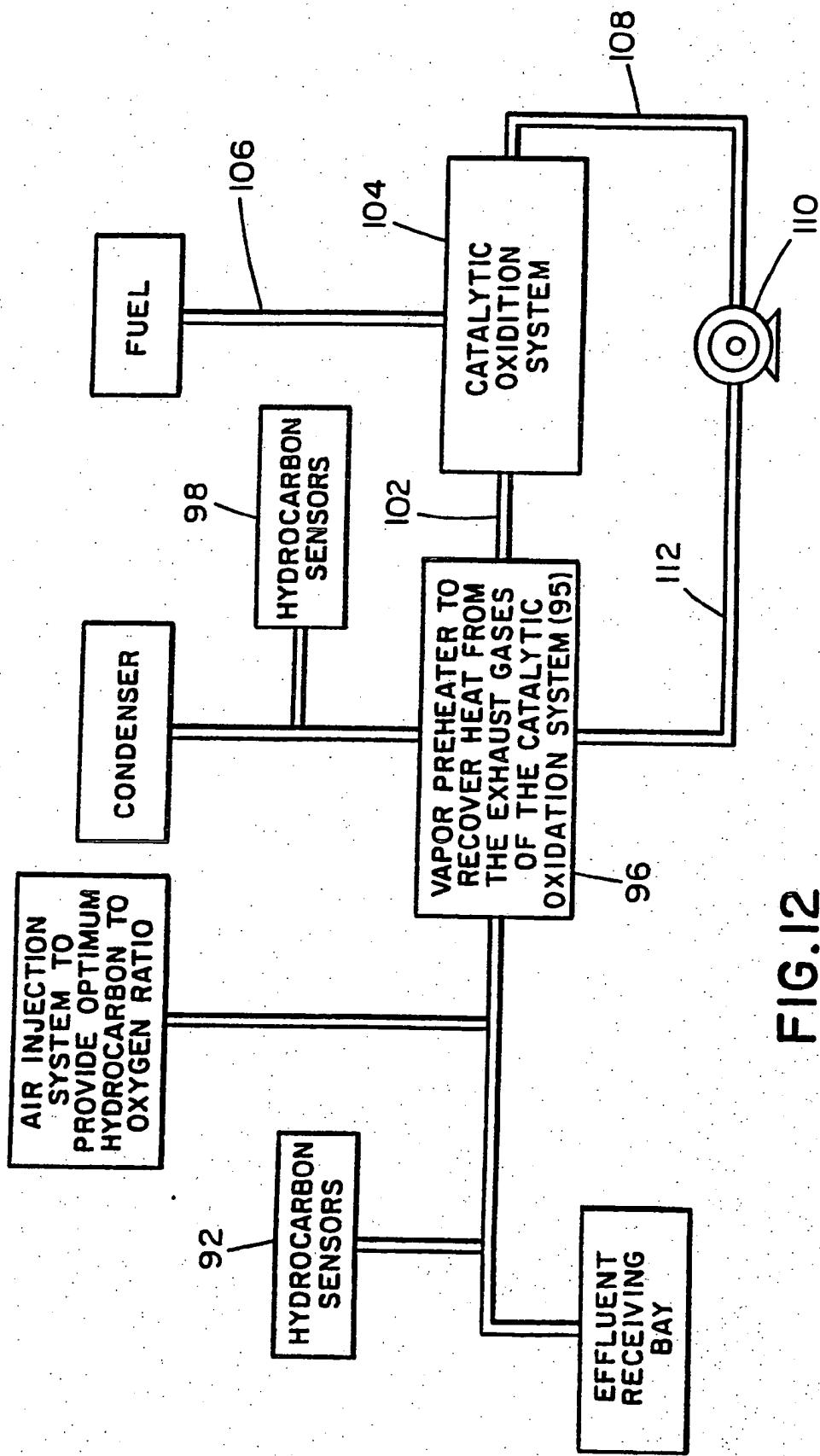


FIG.12

12 / 12

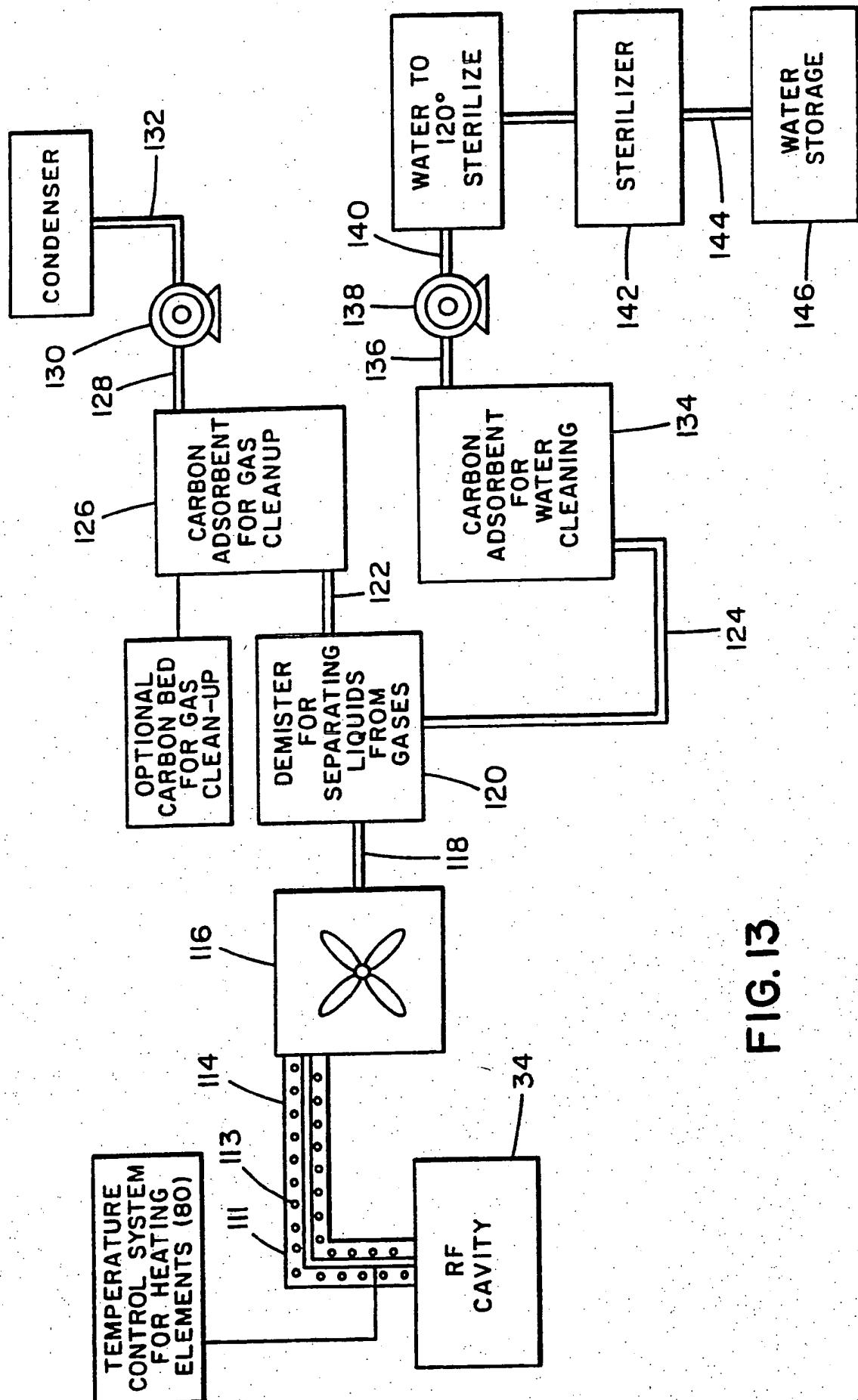


FIG. 13

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US91/02196

I. CLASSIFICATION OF SUBJECT MATTER If several classification symbols apply, indicate all

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): A61L 2/04, 2/12

U.S.Cl.: 422/21, 22

II. FIELDS SEARCHED

Classification System	Minimum Documentation Searched ¹	
	Classification Symbols	
U.S.Cl.:	422/20, 21, 22, 906, 907; 250/492.1	
<small>Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ²</small>		

III. DOCUMENTS CONSIDERED TO BE RELEVANT ³

Category ⁴	Citation of Document, ⁵ with indication, where appropriate, of the relevant passages ⁶	Relevant to Claim No. ⁷
X Y, P	U.S.A., 4,978,501 (DTPROSE et al.) 18 DECEMBER 1990, See Fig. 2 and col. 4, lines 5-7.	1-3, 6, 11, 20-21 4-5, 7-10, 12-14, 22- 23
X Y	U.S.A., 4,207,286 (Gut, Boucher) 10 JUNE 1980, See col. 13, line 41 and Table TT.	1-14, 20, 23 21, 22
X Y	U.S.A., 3,215,539 (TANDY) 02 NOVEMBER 1965, See the entire document.	15, 18, 19 16, 17

* Special categories of cited documents: ¹⁰

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claimed or which is cited to establish the publication date of another citation or other special reason (is specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

* "T" later document published after the international filing date or priority date and not in conflict with the application but used to understand the principle or theory underlying the invention

* "C" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

* "R" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents such combination being obvious to a person skilled in the art

* "D" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

18 June 1991

Date of Mailing of PCT International Search Report

08 JUL 1991

International Searching Authority

ISA/US

Lyle Alexander

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

**IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image
problems checked, please do not report these problems to
the IFW Image Problem Mailbox.**